

**A comparative analysis of the medico-legal and ethical  
issues associated with embryonic stem cell research in  
Australia and Malaysia**

**By**

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# **ABSTRACT**

This thesis evaluates the regulatory framework governing human embryonic stem cell (HESC) research in Malaysia and recommends the adoption of a more effective regulatory model, which is designed to regulate and promote ethical HESC research. The research, which involves the use of donated excess in vitro fertilisation (IVF) embryos and embryos created through the cloning technology, somatic cell nuclear transfer, aims at a better understanding of diseases and could lead to improved medical treatments including cell based therapies, genetically matched to the patient.

This research is controversial as extractions of embryonic stem cells involve the destruction of human embryos, which raises ethical issues. For HESC research to proceed, it is important that an effective regulatory framework that promotes ethical conduct, allays public concerns and ensures transparency and accountability is established. This research argues that the existing regulatory framework in Malaysia needs revision taking into account that scientists generally prefer less regulation to enjoy the scientific freedom to conduct research.

The thesis investigates challenges that exist in the regulation of new technologies with focus on unique challenges for Malaysian regulators. It considers the difficulties in regulating an emerging technology in a multi-religious society with different religions adopting differing perspectives on the research. As a comparison, the thesis evaluates Australia's regulatory framework which has been operating since the early regulation of assisted reproductive technique (ART) in the 1980s when world's first ART legislation was enacted in the Australian state of Victoria in 1984. The thesis evaluates the applicability of the Australian model in the context of a different social environment and concludes with the recommendation of the adoption of an effective regulatory framework. The proposed model is designed to regulate and facilitate ethical HESC research in Malaysia that addresses the regulatory challenges and has features of transparency and accountability.

## **PREFACE**

This thesis is on an evolving and dynamic area with a number of scientific developments as well as legal developments occurring around the world. It takes into consideration the latest scientific and legal developments up to 31 December 2011.

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## STATEMENT OF ORIGINALITY AND AUTHORITY OF ACCESS

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# **PART 1: BACKGROUND TO THE REGULATION OF HUMAN EMBRYONIC STEM CELL RESEARCH, THE SCIENCE AND THE THEORY OF REGULATION**

This thesis critically evaluates the regulatory framework governing the contentious area of human embryonic stem cell (HESC) research in Australia which has a long record of regulating in vitro fertilisation (IVF) and embryo research. It proposes an effective model, based on regulatory theories and is similar to the Australian regulatory framework, for the Malaysian government to adopt to regulate the research. Being Commonwealth nations, these two countries share a common law foundation. However, it is also acknowledged there are marked distinctions in their social, economic, cultural and religious circumstances and these differences will be investigated later in the thesis.

Part 1 sets the context of this thesis. Chapter 1 provides an account of the current regulation of HESC research in Malaysia and the controversies associated with HESC research. This chapter includes the research questions and methodology of this thesis. Chapter 2 explains the science of stem cell research and its importance. Chapter 3 explores the central theme of this thesis: the need for a theory of regulation in the context of HESC research in Malaysia.

# 1: INTRODUCTION

## 1.1 BACKGROUND TO THE REGULATION OF HUMAN EMBRYONIC STEM CELL RESEARCH IN MALAYSIA

Human embryonic stem cell (HESC) research has only recently begun in Malaysia.<sup>1</sup> Malaysia is a developing country with the goal of achieving fully industrialised status in the year 2020<sup>2</sup> and biotechnology has been identified as an engine of economic growth for the country.<sup>3</sup> Ambitious biotechnology plans have been unveiled and in 2005, the National Biotechnology Policy (NBP) was launched by the then Prime Minister, Dato Badawi with health care as an important focus sub-sector of biotechnology. The nine initiatives in BNP, called Thrusts, will realise the country's potential in biotechnology and Thrust 7 provides for 'the creation of an enabling environment through continuous reviews of the country's regulatory framework and procedures in line with the global standards and best practices'.

Most debates on HESC research are conducted in western developed countries like United Kingdom (UK), United States of America (USA) and Australia. The majority of the texts on the subject are written in western countries with western perspectives. The policies, guidelines and law in these countries are also highly developed. However, elsewhere, especially in emerging economies including Malaysia, there is limited literature written on this area and this contributes to the challenge for this thesis.<sup>4</sup> Acknowledging the gap in the literature, the thesis investigates the extent of the research involving HESC in the country and examines if there is a regulatory lacuna in this area.

As HESC research raises issues of deep religious significance, it is especially controversial in a nation which is multi-racial, multi-cultural and multi-religious.

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<sup>1</sup> See Chapter 8.2 of this thesis

<sup>2</sup> The Vision 2020 plan is Malaysia's vision of becoming a fully industrialised and developed country by the year 2020

<sup>3</sup> Malaysian Biotechnology Corporation, *The Malaysian Biotechnology Country Report* (2009/ 2010) is available online at <http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20dou> (15 May 2010) ((15(15 May 2010)(ble.pdf at ES-1 (13<sup>th</sup> May 2010)

<sup>4</sup> See also Chapter 7.7 of this thesis about the interview findings of the views of Malaysian religious leaders on HESC research

Islam is the official religion in Malaysia<sup>5</sup> with the majority of the population being Muslims. There are also significant numbers of Christians, Buddhists, Hindus and Sikhs in the country.<sup>6</sup> Internationally, theologians and representatives for the various religious groups argue both in favour of and against HESC research. There is a lack of consensus about the moral status of the human embryo as well as the ethics and morality of research using embryos. The cultural and religious diversity of a society makes the task of reaching a consensus challenging.

Concerns about cloning and HESC research came to public attention in 1997, when Dolly, the sheep and the first cloned mammal, was born. The creation of Dolly heightened concerns about the possibility of cloning human beings.<sup>7</sup> It also led to debate on appropriateness of allowing therapeutic cloning/ somatic cell nuclear transfer (SCNT) which shares the same technology with reproductive cloning. One of the difficulties in this area is that the debate about cloning and HESC research is often conflated.

HESC research has significant medical importance offering the promise of cures for patients suffering from various diseases. As master cells, stem cells can give rise to wide range of cells and tissues. They are blank cells, or slates, that have yet to become specialised. Unlike fully mature cells, they have a variety of potential futures.

The types of stem cells used in research are adult stem cells<sup>8</sup> and HESCs. Stem cells from embryos are pluripotent, that is, they can grow into every tissue type in the body. They could become any type of cell to form skin, bones, organs and other body parts. They could be used to create any number of cell types that people with injuries or disease in need of transplants might benefit from receiving. Whilst doctors can transplant tissues and organ cells, they are often limited by lack of

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<sup>5</sup> Article 3 of the Federal Constitution of Malaysia

<sup>6</sup> According to the Department of Statistics Malaysia, the demographics of the Malaysian population are 60.4% Muslims, 19.2% Buddhists, 9.1%, Christians, 6.3% Hindus and others which include Sikhs. See <http://www.statistics.gov.my/portal/index.php?lang=en> (13 May 2010)

<sup>7</sup> Reproductive cloning is not the central theme in this thesis. This practice is prohibited in many nations

<sup>8</sup> Bone marrow transplantation for leukaemia patients is a good example of adult stem cell therapy and it has been available for the past 30 years

organ donors. Potentially, stem cells will allow the growth of required tissue when it is needed.

Research utilising HESCs remains in early stages, making it uncertain whether stem cells derived from human embryos will ultimately prove useful in curing diseases and spinal cord injuries. It is premature to decide which approaches will prove most useful and for which diseases. Due to the unsettled state of the science, stem cell research, both adult and embryonic, is being funded by public and private funding agencies around the world in order to make the potential of stem cells a reality. However, there are several important ethical issues with HESC research that have to be explored and addressed.

## **1.2 THE CONTROVERSIES OF HESC RESEARCH IN MALAYSIA**

In many nations, including multi-religious Malaysia, HESC research has been, and is increasingly the subject of controversy, primarily because all extractions of HESCs involve the destruction of human embryos. The debate is discussed within various religious institutions and with people of different faiths. In laboratories, scientists have had to learn to reflect on the ethical and legal ramifications of their work. Despite the controversy, it is argued here that the promise of HESC research is probably sufficient justification to allow it to proceed, provided that it is governed by strict regulations and effective enforcement procedures.<sup>9</sup> This thesis will investigate options for regulating this controversial research and propose a best practice regulatory model for Malaysia.

The destruction of human embryos for the purposes of extracting HESCs presents an ethical and moral dilemma. Proponents of HESC research argue that it could lead to therapies for the patients in future. Opponents argue that the research has uncertain prospects and involves a process that destroys human lives. These two opposing positions reflect different views in respect to whose life matters more, whether the lives of patients or the lives of human embryos which are destroyed in the process of harvesting their stem cells for research. The argument raises

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<sup>9</sup> It is noted that HESC research has already begun in both Australia and Malaysia

questions about the obligation to heal patients, the respect and protection owed to nascent human lives, and the manipulation of human lives for the benefit of others.

The moral debate includes whether it is morally and ethically wrong to first create and then destroy a human embryo, whether cloned or not, in order to harvest its cells, and the concern about the treatment of nascent human life, that is, treating the seeds of the next generation as mere raw material for satisfying current human needs. While it is important to seek and provide medical treatment for patients and the injured, it is also important to honour moral limits that respect all lives and that refuses to secure the good of human beings by sacrificing the lives of others.

These are difficult questions. The moral issue surrounding HESC research leaves the status of the embryo highly contested. It is unclear whether human embryos are legally and morally considered as human lives from the moment of conception or at some later stage of development. This thesis explores the various definitions of a human embryo<sup>10</sup> and discusses its moral status.<sup>11</sup>

Other ethical issues also arise from HESC research, particularly concerns about the exploitation of women and the risk that the therapeutic cloning research may lead to reproductive cloning. This thesis takes the position that it is morally permissible to use early stage human embryos in research under strict regulation as that would not transgress moral boundaries.

These arguments focus broadly on whether the human embryo has meaningful interests and moral rights sufficient to justify the prohibition on HESC research. This raises the question whether the early embryo in the first 14 days should be regarded as a human embryo or a collection of cells and therefore considered a pre-embryo. The destruction of the embryo, for the purposes of the extraction of stem cells from it, occurs around the fifth day after the first cleavage division.<sup>12</sup> Questions are also raised as to whether the somatic cell nuclear transfer (SCNT) blastocyst, which does not involve egg and sperm fertilisation, should be regarded

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<sup>10</sup> See Chapter 2.6 of this thesis

<sup>11</sup> See 1.3 this chapter. See also Chapter 7 which explores the moral status according to each main religion in Malaysia

<sup>12</sup> See Chapter 2.6 of this thesis

as a human embryo as there is no evidence that the blastocyst, if implanted in the body of a woman, can result in a live birth.

These debates have been explored extensively in Australia<sup>13</sup> but in Malaysia, the discussions are both less advanced and more diverse.<sup>14</sup> This thesis will explore these controversies from both the Australian and the Malaysian perspectives.

### 1.3 THE MORAL STATUS OF A HUMAN EMBRYO

The discussion of the moral status of an embryo can be traced back to the pre-Socratic philosopher Heraclitus.<sup>15</sup> Aristotle wrote of the ensoulment of the human at a particular stage.<sup>16</sup> In the western world, since the sexual revolution of the 60s, with the discovery of birth control pill and debates on the legality of abortion, there have been ongoing debates on the moral status of the human embryo with the question of ‘when ensoulment occurs’.<sup>17</sup> In 1978, when the world’s first in vitro fertilisation (IVF) baby/ ‘test-tube baby’ was born,<sup>18</sup> the debate re-emerged in a report in the UK.<sup>19</sup> In 1997, the creation of Dolly, the sheep, generated new debates on issues arising from cloning and stem cell research, which included the moral debate of human embryos as evident in the reports in countries like the USA<sup>20</sup> and Australia.<sup>21</sup> At present, this continues to be a debateable issue in the discussion of the use of reproductive technologies not only in the western world but also in other societies such as the Muslim world.

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<sup>13</sup> See Chapter 4-6 of this thesis especially the Parliamentary debates in Chapter 5

<sup>14</sup> The discussions are diverse as there are a number of different religions in the nation. See Chapters 7-9 of this thesis

<sup>15</sup> McGee G, Patrizio P, Kuhn V & Roverson-Kraft C, ‘The Ethics of Stem Cell Therapy’ in McGee G & Caplan A (eds), *The Human Cloning Debate*, Berkeley Hills Books, Berkeley, 2004 at 44

<sup>16</sup> Ibid

<sup>17</sup> *Roe v. Wade* 410 U.S. 113 (1973)

<sup>18</sup> The birth of Louise Brown

<sup>19</sup> Department of Health & Social Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984) Cmnd 9314 (Warnock Report)

<sup>20</sup> President Council’s on Bioethics, *Human Cloning and Human Dignity: The Report of the President’s Council on Bioethics* (President’s Council Report), Public Affairs, New York, 2002

<sup>21</sup> Australian Health Ethics Committee of the National Health Medical Research Council, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings* (1998) Canberra (AHEC Report), House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001) Canberra (Andrews Report). See Chapter 4 of this thesis



The key to the argument of the moral status of the human embryo is the moment at which personhood or a soul is acquired.<sup>22</sup> With reference to western academic literatures, this notion is debated ethically with three different views put forward. The first view, on one end of the continuum, is that the human embryo has no intrinsic moral status and therefore its destruction is not inherently morally problematic. The reason is that the early embryo is not yet endowed with the properties of sentience or rationality. As Professor Russell Blackford argues:

The early embryo does not fear death, incapable of planning, of identifying with political causes or falling in love, with no networks or kin, loved ones, dependents or colleagues and cannot commit itself to any projects that give it reason or to want to go on living and developing. It has no wants.<sup>23</sup>

Professor Judith Jarvis Thomson claims that the best metaphor to describe the status of the embryo is that of a parasite, possessing no moral status independent of the mother.<sup>24</sup> It depends completely on the mother for its development. Only at the time of birth is the baby recognised as a person. Prior to that, the embryo is merely a bundle of cells, waste product or by-product of the ART programme.<sup>25</sup> The biological definition claims that the embryo takes on pre-human structure on the 14<sup>th</sup> day after conception.<sup>26</sup>

The second view, at the other extreme, is that the human embryo has intrinsic moral and legal status equivalent to a baby or an adult. From the point of conception/fertilisation, that is, when the sperm meets the egg, the development of the person begins. At this moment, the individual DNA code is imprinted in the embryo, signifying the beginning of a new human existence and the identification of the human.<sup>27</sup> The creation of a person is linked to the consummation of an act by participants in its creation. As the moral status of the embryo equates to an adult

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<sup>22</sup> The concept of ensoulment is explained in Chapter 7 of this thesis

<sup>23</sup> Professor Russell Blackford of the School of Philosophy and Bioethics, Monash University. Blackford R, 'Stem Cell Research on Other Worlds or Why Embryos Do Not Have a Right to Life', (2006) *Journal of Medical Ethics* 177-180

<sup>24</sup> Professor Judith Jarvis Thomson, a philosopher at the Massachusetts Institute of Technology (MIT). McGee G, Patrizio P, Kuhn V & Roverson-Kraft C, 'The Ethics of Stem Cell Therapy' 37-56 in McGee G & Caplan A (eds), *The Human Cloning Debate*, Berkeley Hills Books, Berkeley, 2004 at 45

<sup>25</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? Part II' (2003) 18 *Law and the Human Genome Review* 91-108 at 99

<sup>26</sup> See Chapter 2.6 of this thesis

<sup>27</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values?' at 98

human being, it is considered that it is morally wrong to harm the embryo, even for a good cause. In addition, the use of an embryo for research purposes is considered to be the exploitation of a vulnerable subject in research without his or her consent; research that presents not only a great risk but has the predictable outcome of death for the subject. It is argued that this is contrary to the *United Nations Declaration on the Rights of the Child 1959*,<sup>28</sup> the preamble of which states:

the child, by reason of his physical and mental infirmity, needs special safeguards and care, including appropriate legal protection, before as well as after birth.

The third view lies somewhere in between these two extremes: the embryo enjoys some moral status but less than an adult human being. In *Roe v Wade*,<sup>29</sup> the Supreme Court of the USA held that pregnancy could be divided into three periods, three trimesters with each period corresponding to the degree to which the human embryo has developed, that is, each period represents the increasing standing of the emerging human person in the community. An embryo begins with little or no moral status and, as it develops, it attains more status and continues to attain more.

With reference to an important point raised by the President's Council report:

In our view, embryos have a developing and intermediate moral worth, such as that the early human embryo has a moral status somewhere between that of ordinary human cells and that of a full human person. We acknowledge the difficulty of setting perfectly clear line marking when an embryo's moral status goes from "less than a human person" to "like a human person" to "full a human person." But we believe there are sound moral reasons for not regarding the embryo in its earliest stages (certainly in the first fourteen days) as the moral equivalent of a human person, though it does command significantly more respect than other human cells. We also hold that the embryo can be used to life-saving to potentially life-saving it deserves, and while still preventing abuses such as research on later-stage embryos or fetuses or the production of cloned children ...<sup>30</sup>

This report refers to the example of the practice of sacrificing the life of the unborn foetus in order to save the life of a pregnant woman. It claims that this reveals 'moral precedent for subordinating nascent human life to a more developed human life.'<sup>31</sup> The report also provides that it is possible to accord the embryo with due

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<sup>28</sup> G.A. res. 1386 (XIV), 14 U.N. GAOR Supp. (No. 16) at 19, U.N. Doc. A/4354. This declaration is only advisory and not legally binding

<sup>29</sup> 410 U.S. 113 (1973)

<sup>30</sup> President's Council Report at 153

<sup>31</sup> Ibid at 155-156

respect while using it for research.<sup>32</sup> By analogy, it cites the example of hunters, who may have respect and even affection for the animals they kill. It argues that the embryos should be given the respect in that they are used for serious and not frivolous reasons.

This third view is most persuasive. While the embryo is at a very early stage of development, that is, the fifth day after conception when it is destroyed, it should still be accorded special respect. However, this does not prevent its use in research under strict conditions. Provided HESC research is conducted within a strict regulatory framework, it is permissible to destroy human embryos for the purposes of the research.

Given Malaysia has different demographics and an overall different cultural environment, it is noted that these three views widely debated in western literature are not strictly influential in Malaysia. As mentioned, this nation is a multi-religious Muslim country with large numbers of adherents of various faiths. This thesis will investigate these differences and Chapter 7 of this thesis explores the various interpretations of the moral status of the human embryo according to the main religions in Malaysia, which vary considerably.

## **1.4 ARGUMENTS IN FAVOUR OF AND AGAINST HESC RESEARCH**

As mentioned in 1.2 and 1.3 of this chapter, there are a number of arguments in favour of and against HESC research. Each of these points of contention is explored below. The Australian Legislation Review Committee Report (Lockhart Report)<sup>33</sup> is a valuable source of these discussions, as many submissions to the Inquiry raised these arguments and were dealt with in the report.<sup>34</sup> Most of these arguments are universal and thus relevant in other contexts including the Malaysian context.

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<sup>32</sup> Ibid at 156-157

<sup>33</sup> This is an Australian government report written by an independent legislation review committee that contains important and comprehensive review of the Australian legislation relating to human cloning and research involving human embryos, that is, the *Prohibition of Human Cloning Act 2002 (PHC Act 2002)* and the *Research Involving Embryos Act 2002 (RIHE Act 2002)*

<sup>34</sup> This report is explored further in Chapter 4, 5 and 6 of this thesis

### 1.4.1 ARGUMENTS FOR HESC RESEARCH

#### *Facilitating basic research*

An important argument in support of HESC research is the facilitation of basic research. HESCs have potentially useful applications in areas of medical research, for instance, studying cell differentiation in healthy and diseased tissues as well as disease modelling studies.<sup>35</sup> HESCs can be grown in laboratory culture for long periods without losing their pluripotency and are capable of self-renewal.<sup>36</sup> HESC research will likely enable scientists to study and understand early human development, cell division and the development and progression of diseases. It may provide important clues into the origin of birth defects, the ageing process and the way alterations in cell division are involved in producing cancer. As stated in one submission to the Lockhart inquiry:

... to generate disease-specific stem cell lines that could be used to better understand in the laboratory the progression of complex diseases such as diabetes, motor neuron disease, Huntington's and Parkinson's diseases.<sup>37</sup>

To facilitate the study of particular diseases, stem cells with specific genetic traits can be isolated. For example, to study the origins of an inherited disease, stem cells made from egg and sperm donors who have this disease or are carriers could be used.

Some submissions to the Lockhart inquiry commented on the usefulness of HESC research for drug screening. For example, one submission noted that:

... the use of human embryonic stem cell lines ... could prove of great value to the pharmaceutical industry in initial stage screening of new drug candidate ... also the discovery of better medicines that can reach the clinic sooner.<sup>38</sup>

The Lockhart Committee found scientific merit in the use of HESCs for this type of research.<sup>39</sup> The stated rationale was that such research could increase the understanding of disease processes and lead to treatments for diseases. While the Committee acknowledged the advances in research into adult stem cells which have already been used successfully in the treatment of some human diseases, such as

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<sup>35</sup> Lockhart Report at 62

<sup>36</sup> These are important characteristics of HESC. See Chapter 2.5.2 of this thesis

<sup>37</sup> Lockhart Report at 62, submission by Stem Cell Sciences Ltd

<sup>38</sup> Ibid

<sup>39</sup> Ibid at 166-167

bone marrow transplantation, pursuing HESC research alongside adult stem cell research is important.<sup>40</sup>

#### *Potential therapeutic benefits*

The potential of the therapeutic benefits is an important argument for the conduct of HESC research.<sup>41</sup> Some degenerative diseases cannot be treated pharmaceutically but require the replacement of damaged cells. HESC lines<sup>42</sup> could eventually be used to develop cells, tissues and eventually organs for transplantation. First, HESCs are pluripotent and are capable of producing most cell types in the body. Secondly, cloned cells are likely to be useful in the medical treatments of diseases as there is less risk of tissue rejection. The cells would be genetically matched to the patient needing a transplant, making it less likely that his/ her body would reject the new cells than it would with traditional tissue transplant procedures. Thirdly, scientists hope to be able to grow organs that enable doctors to transplant tissue and organ cells, which lie against the backdrop of a shortage of organ donors, and consequent lengthy waiting lists for patients needing organ transplantation. SCNT technology may allow organs and tissues to be grown as and when they are needed.<sup>43</sup> The research, if translated to therapy, has the advantages of addressing such serious issues. The benefits are potentially so great that a case could be made for saying that it would be immoral not to pursue the research.

#### *Use of excess IVF embryos*

Excess IVF embryos are already destroyed routinely by allowing them to thaw from their frozen state as required by the legislation in various states.<sup>44</sup> In the Lockhart Report, the Committee perceived that on balance, there was support for the use of excess ART embryos for destructive research, both for ART research and to obtain HESCs.<sup>45</sup> This view was expressed by most scientists, many organisations and individuals,<sup>46</sup> and was shared by ART consumers, many of whom have donated

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<sup>40</sup> Ibid at 170

<sup>41</sup> See Chapter 2 of this thesis

<sup>42</sup> Ibid

<sup>43</sup> See Chapter 2.5.2 of this thesis

<sup>44</sup> See Victoria's *Infertility Treatment Act 1995*, South Australia's *Reproductive Technology Act 1988* and Western Australia's *Human Reproductive Technology Act 1991*

<sup>45</sup> Lockhart Report at 77

<sup>46</sup> Ibid

their excess embryos for research.<sup>47</sup> A number of submissions indicated that many couples preferred their embryos to be used for research rather than wasted.<sup>48</sup> However, it was argued in some submissions that all uses of human embryos should be prohibited.<sup>49</sup> After careful consideration of the submissions, the Committee concluded that the use of excess ART embryos to derive HESCs has contributed to the progress in understanding stem cells and research directed to future therapeutic outcome of the research.<sup>50</sup> It added that developments in adult stem cell research do not remove the need to conduct HESC research and agreed with the view of many researchers that both types of research should be allowed to proceed.<sup>51</sup> The Committee concluded that, with the broad range of diseases and conditions that may be treated by therapies developed from stem cell research, the number of patients who could benefit from this research is high. Therefore, excess ART embryos which are going to be discarded any way should not be wasted but should be used for a worthwhile cause such as research.

#### *Deliberate creation of embryos for good cause*

One of the main reasons for opposition to HESC research, whether the HESCs are extracted from excess IVF embryos or embryos created by SCNT, is that it involves destruction of human embryos. However, the excess ART embryos that are sacrificed are not deliberately created for destruction, but for the use in the service of life and medicine. On the other hand, it must be acknowledged that SCNT embryos are deliberately created for research purposes.

The Lockhart Committee considered the argument that cloned embryos should not be created in order to be destroyed,<sup>52</sup> but was not persuaded. Because IVF embryos are already being lawfully destroyed in great quantities, it would be inconsistent not to accept the destruction of cloned embryos. Moreover, allowing the destruction of IVF embryos but not SCNT embryos appears to place greater importance to the treatment of infertility than the treatment of serious diseases. In view of the wide range of diseases and conditions that could be treated as a result of this activity, the

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<sup>47</sup> Ibid at 166

<sup>48</sup> Ibid at 78

<sup>49</sup> Ibid at 77-78

<sup>50</sup> Ibid at 166

<sup>51</sup> See also the discussion under subheading *Preferable Alternatives* in this chapter

<sup>52</sup> Lockhart Report at 170

Committee considered that further research using cloned human embryos should be permitted.<sup>53</sup> The deliberate creation of embryos for research is for a good cause, that is, in the service of life and medicine that will benefit society and it should therefore be permitted.

*Pursuing research within reasonable bounds*

This argument raises the principle of proportionality in considering research. Experience in some jurisdictions has shown that HESC research can be carried out within reasonably proportionate bounds with strict regulations and the enforcement of the regulations. For instance, in Australia, the relevant legislation, the *Research Involving Human Embryos (RIHE) Act 2002* (Cth), creates a national scheme whereby researchers are licensed for each research project that involves use of an embryo.<sup>54</sup> The key feature of the scheme is a licensing regime restricted to the use of excess ART embryos, that is, those embryos that have been created in order to achieve a pregnancy but which, after a period of frozen storage, are no longer needed for this purpose, (for example, the progenitors of the embryos no longer need them.) The aim of the scheme is to allow research on human embryos but only in limited circumstances. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Amendment Act 2006) which, *inter alia*, amended the *RIHE Act 2002*, permits research on cloned embryos but the approval to be granted is strictly limited to the first 14 days of development, a point when the primitive streak is formed and before organ differentiation occurs.

*Economic benefits, scientific implications and preventing brain drain*

The potential economic benefits to be gained from HESC research, the need for scientific leadership in Australia and the risk that scientists will move to other countries to undertake their research (a stem cell brain drain) were all considered in the Lockhart Report to be important arguments favouring HESC research and its regulation. HESC research is recognised as being important for the nation economy and the future of the biotechnology industry. This research, important in itself, will

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<sup>53</sup> Ibid

<sup>54</sup> This is explored further in Chapter 4.6.2 of this thesis

create jobs in the country's scientific community that would otherwise be lost to other countries conducting the research.<sup>55</sup>

The Lockhart Committee acknowledged that HESC research is proceeding in some nations where these technologies are legally permitted or where no effective national legislative regulation is in place.<sup>56</sup> Many submissions argued that the law should permit Australian researchers to contribute to the intellectual and biotechnological developments in the field.<sup>57</sup> It was further argued that prohibition of the research would put Australian researchers at a disadvantage in terms of exploring possible new treatments, which had serious implications for Australian research and the availability of new therapies.<sup>58</sup>

#### **1.4.2 ARGUMENTS FOR HESC RESEARCH IN MALAYSIA**

While the foregoing arguments in favour of HESC research were explored specifically in the Australian context in the Lockhart Report, these points of contention are also relevant in the Malaysian context. An important argument in favour of pursuing HESC research in a Muslim country is that the use of excess IVF embryos in research is currently permitted by the Islamic faith as this religion adopts liberal interpretations of the concept of ensoulment of the human embryo.<sup>59</sup>

In addition, encouraging and permitting HESC research in Malaysia has the capacity to bring forth economic benefits to the country, especially being an emerging economy<sup>60</sup> and may also assist in preventing brain drain in the nation.<sup>61</sup> The Malaysian government is supportive of biotechnology, as reflected in the nation's National Biotechnology Policy (NBP). However, if adequate regulations

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<sup>55</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values?' at 101

<sup>56</sup> Lockhart Report at 170

<sup>57</sup> Ibid at 137-138

<sup>58</sup> Lockhart Report at 63

<sup>59</sup> Ensoulment means the moment the embryo receives the soul. In Islam, there are two schools of thoughts, both of which are liberal. The present *Fatwa* (Islamic religious legal opinion) in Malaysia permits HESC research using excess IVF embryos; see Chapter 7.2 of this thesis

<sup>60</sup> NBP Policy

<sup>61</sup> The government attempts to lure its overseas graduates to return to Malaysia through its 'Brain Gain Programme', see [http://www.mosti.gov.my/mosti/index.php?option=com\\_content&task=view&id=365&Itemid=251](http://www.mosti.gov.my/mosti/index.php?option=com_content&task=view&id=365&Itemid=251) (12 December 2011)



are not put in place to both support and control stem cell research, the whole endeavour could flounder and the brain drain of scientists from the nation could be a real and serious possibility. Therefore, it is argued that HESC research should be facilitated in Malaysia within reasonable bounds by adopting a tight regulatory framework.

### **1.4.3 ARGUMENTS AGAINST HESC RESEARCH**

Having explored the arguments in favour of HESC research, this section explores the points of contention against the research. Once again, the Lockhart Report is a valuable source of these discussions. While a number of these arguments are relevant in the Malaysian context, there are some which are not strictly relevant (see 1.4.4 of this chapter).

#### *The human embryo being regarded as a person and the exploitation of a developing human life*

The main concern raised against HESC research arises where the human embryo is regarded as having the equivalent moral and legal status to a person, whether of a baby or adult.<sup>62</sup> It is reasoned that the creation of human life expressly and exclusively for the purpose of its use in research amounts to exploitation of a developing human life. Permitting HESC research is tantamount to approving the transformation of nascent human life into a mere resource or tool. For those individuals who view the human embryo as a fully formed human being, its destruction is equivalent to the commission of the crime of murder and HESC research is, accordingly, immoral and unethical, and should be prohibited.<sup>63</sup>

#### *Possible development of cancer*

This argument raises a serious concern about the possible carcinogenic potential of HESCs. It has been argued that HESCs may contain rare cancer stem cells that have a tendency to generate tumours (such as teratomas) and may also differentiate into unwanted cell types.<sup>64</sup>

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<sup>62</sup> See 1.3 of this chapter

<sup>63</sup> This is the argument put forward by some religions such as the Roman Catholic faith. See Chapter 7.3 of this thesis

<sup>64</sup> *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies*, National Academies Press, Washington DC, 2006 at 5

### *Exploitation of women in research*

A significant argument against permitting the use of SCNT for HESC research is that even though it does not involve the destruction of excess ART embryos, it still requires the use of human eggs. Serious ethical concerns have been raised about the potential for the exploitation of women concerning egg donation for SCNT. These concerns include the possible coercion on vulnerable people. This issue came to the fore in 2006 in South Korea, in relation to the so-called the Hwang debacle. Media agencies reported that young female research staff were being requested to donate their eggs for research.<sup>65</sup>

Permitting SCNT is likely to lead to an increased demand for donated eggs, particularly from young women who have better quality eggs than older women. As a submission to the Lockhart inquiry argued: ‘... you’re going to want really good eggs. You’re going to need healthy eggs and so you’re going to try to get them from a young woman.’<sup>66</sup> The risk is that younger women may be more susceptible to coercion, because of lack of maturity or other pressures.

There are also health risks, real and potential, short and long term, involved with ovarian stimulation and egg collection.<sup>67</sup> These risks include morbidity or mortality associated with the hormone treatment required for egg retrieval and they far exceed the risks associated with the removal of other tissues for research.

### *Slippery slope to more contentious research*

According to this frequently-used argument, permitting HESC research is at the edge of a slippery downward slope to more ethically questionable research, with Frankenstein disasters.<sup>68</sup> For instance, successful SCNT for therapeutic purposes would make it easier and more tempting for scientists to attempt reproductive cloning. It could also create a demand for human embryos leading to the

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<sup>65</sup> Resnik D, Shamoo A, Krinsky S, ‘Fraudulent Human Embryonic Stem Cell Research in South Korea: Lessons Learned’ (2006) *NIH Public Access Author Manuscript* 101-109

<sup>66</sup> Submission by Sister Regis Mary Dunne at 21 of Lockhart Report

<sup>67</sup> Pearson H, ‘Health effects of Egg Donation May Take Decades to Emerge’ (2006) 442 *Nature* 607-608, Mertes H & Pennings G, ‘Oocyte Donation for Stem Cell Research (2007) 22 *Human Reproduction* 629-634

<sup>68</sup> Chalmers D & Nicol D, ‘Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values?’ at 100

development of tissue banks and mass production of human eggs, the creation of designer babies and sex selection of babies.<sup>69</sup>

#### *False assurance*

Developing new medicines/ treatments is countered by warnings that it is wrong to offer patients false hope. If HESC research is allowed to proceed, it would take years before any therapies come out of the research.<sup>70</sup>

#### *Preferable alternatives*

This argument maintains that HESC research does not need to be pursued as there are viable and ethically preferable alternative research pathways. It is argued that scarce resources should be directed only towards to adult stem cell research<sup>71</sup> and other stem cell alternatives, such as the recent important scientific breakthrough of induced pluripotent stem cells (IPS), where adult cells, such skin cells, are induced or reprogrammed into HESCs like state. There have been some documented success stories on the use of adult stem cells and the more established stem cell treatment using bone marrow transplants for some blood diseases.<sup>72</sup> The potential to deliver meaningful medical results and therapies appears promising, and many of the ethical problems with HESC research are avoided. The potential to gain widespread ethical acceptance of adult stem cells is greater than for HESC research. Many religious groups, especially the Catholic church, are in favour of this type of research.<sup>73</sup> In addition to adult stem cell research, there are stem cell alternatives including a number of innovative methods that overcome some of the ethical problems in deriving HESCs.<sup>74</sup>

#### *Commercial exploitation*

This argument raises the concern that HESC research that has a strong commercialisation aim denigrates respect for the embryo. The risk is that embryos will be treated as commodities where market driven decisions take precedence over

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<sup>69</sup> Ibid

<sup>70</sup> See Chapter 2.9 of this thesis

<sup>71</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic values?' at 99

<sup>72</sup> See Chapter 2.5.1 of this thesis

<sup>73</sup> See Chapter 7.3 of this thesis

<sup>74</sup> The six innovative ways are described in Chapter 2.7 of this thesis

ethical decisions. Concerns have been raised that benefits and profits should be in the public domain and therapies must be available within the public health system.<sup>75</sup>

Presently gametes and embryos are donated altruistically, which would seem to negate concerns about commercialisation at the early state of donation.<sup>76</sup> However, the shortage of human eggs,<sup>77</sup> a vital ingredient for SCNT, has caused some to question whether female donors should be paid a fair price for their eggs to encourage more donors to come forward. While most submissions to the Lockhart review opposed payment for eggs, others were in favour of reimbursing donors for out-of-pocket expenses, such as transport and loss of wages.<sup>78</sup>

#### *Moral harm to society and what the present and future world is owed*

This argument raises the fear that permitting HESC research could lead to significant moral harm by transforming the current society to a different one ‘that mandates the destruction of nascent human life’.<sup>79</sup> A similar argument raised against the research is that the legacy to leave, to both present and next generation, is a world that honours moral limits and respects all life.<sup>80</sup>

#### **1.4.4 ARGUMENTS AGAINST HESC RESEARCH IN MALAYSIA**

While many of the arguments against HESC research explored above are relevant in the Malaysian context, there are some contentions that are not strictly relevant. First, on the argument that the human embryo is regarded as a person, it is noted that according to the Islamic faith, the interpretation adopted is that an early five day old human embryo is not yet considered a person as it is not ensouled during that very early stage.<sup>81</sup>

Secondly, as for the contention that permitting HESC research could cause slippery slope to even more contentious research such as human reproductive cloning, it is

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<sup>75</sup> Lockhart Report at 140

<sup>76</sup> Ibid

<sup>77</sup> Maher B, ‘Egg Shortage Hits the Race to Clone Human Stem Cells’ (2008) 453 *Nature* 828-829, Vogel G, ‘Picking Up the Pieces after Hwang’ (2006) 312 *Science* 516-517

<sup>78</sup> Lockhart Report at 133-135

<sup>79</sup> President’s Council Report at LV-LVI

<sup>80</sup> Ibid at LVI

<sup>81</sup> See Chapter 7.1 of this thesis

noted that while Islam has expressed condemnation of human cloning, there are other faiths that appear to endorse the practice.<sup>82</sup> In any event, it is argued that human reproductive cloning and other contentious activities like the creation of designer babies and sex selection could be strictly regulated by passing legislation to prohibit them and HESC could still proceed with strict regulation.

Despite the concerns and arguments raised against HESC research, it is nevertheless argued that, on balance, this contentious research should be pursued in Malaysia. Accordingly, it is critical for the Malaysian government to adopt a strict regulatory framework to regulate HESC research to ensure transparency, accountability and ethical research.

## **1.5 THE JUSTIFICATIONS FOR THE POSITION THIS THESIS TAKES ON HESC RESEARCH**

The controversial nature of HESC research is acknowledged, however this thesis takes the position that the research should be pursued. In accordance with the third view of personhood discussed in 1.3 of this chapter which broadly reflects the Islamic position, the human embryo should not be accorded the same moral status as a person and accordingly, research on early embryos, provided that it is in accordance with strict criteria, is ethically permissible.

While it is acknowledged that some of the risks associated with HESC technology remain unknown, particularly the possible development of cancer, HESC techniques will improve and be perfected over time. This is evidenced in the conduct of IPS technology where in the last three years in different parts of the world, there has been improvement and refinement of this technique, which enhances safety.<sup>83</sup> Uncertainties in science make it even more imperative to pursue the research to increase scientific knowledge and facilitate better understanding of diseases.

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<sup>82</sup> Islam categorically forbids human reproductive cloning as it is against the natural process/*fitrah* of human relationship of marriage and reproduction. However, other faiths such as Hinduism and Buddhism appear to endorse human cloning; see Chapter 7.4 and 7.5 of this thesis. It is beyond the scope of this thesis to explore further the arguments for and against human reproductive cloning

<sup>83</sup> See Chapter 2.7.6 of this thesis

Because it takes time for research to be translated into therapy, it is reasonable that HESC research should not be necessarily delayed, and should begin sooner rather than later. A submission in the Lockhart Report recognised that many of the claims about HESC benefits need to be tested in research:

controlled ethically approved ... research should be approved to appropriately licensed institutions to ascertain whether this form of technology may prove beneficial in the future. Without the research, we will never know.<sup>84</sup>

While there may be preferable stem cell alternatives such as the innovative IPS approach, many scientists remain cautious. IPS is in early stages and the published studies are open to multiple interpretations or require replication with crucial scientific issues to be resolved. It is a slow and inefficient process that requires weeks with most cells failing to reprogram<sup>85</sup> and the efficiency of IPS, at only 1%, is very low.<sup>86</sup> The new findings do not lead to a conclusion that HESC research is no longer needed. Similarly, adult stem cells and HESCs are not alternatives but complementary pathways to therapy. More research is needed before ascertaining the best routes for therapies. Even if the potential of adult stem cell-based therapies is realised, it is unlikely that they will fulfil all therapeutic needs. Ethical concerns should not lead to the abandonment of an important avenue of research. To pursue adult stem cell research, to the exclusion of HESC research, is limiting and it is recommended that all types of stem cell research should be pursued.

Many concerns raised about HESC research could be adequately dealt by strict regulation as illustrated by the Australian approach discussed in detail later in this thesis. First, the slippery slope argument can be discounted as the consequences of HESC research should be able to be controlled by way of regulation and prohibition. For example, in Australia, the *Prohibition of Human Cloning Act 2002* (*PHC Act 2002*) prohibits human reproductive cloning.<sup>87</sup> Regulation could also be introduced to prohibit the creation of designer babies and sex selection, along the same lines as the Australian regulatory framework which prohibits human

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<sup>84</sup> Submission by Dr Stephen Junk at 65 of Lockhart Report

<sup>85</sup> Mikkelsen T et al, 'Dissecting Direct Reprogramming through Integrative Genomic Analysis' (2008) 454 *Nature* 49-55

<sup>86</sup> Costello J, 'Tips of Priming Potency' (2008) 454 *Nature* 45-46

<sup>87</sup> Section 9 of *PHC Act 2002*

cloning.<sup>88</sup> It is therefore argued that strict regulation of these activities is achievable and that Malaysian regulators should consider taking similar steps.

Concerns about commercialisation misunderstand the need for commercial investment in downstream research and development activities. The Lockhart Committee recognised that commercialisation is an essential aspect of research and without investment, new therapeutic products cannot be developed<sup>89</sup> and recommended that the concerns raised could be adequately dealt with by guidelines as illustrated in the Australian regulatory framework.<sup>90</sup> The Committee also concluded that the serious concerns relating to the possible exploitation of women in research, can be controlled through strict regulation.<sup>91</sup> This argument again illustrates the crucial role of regulation and should encourage Malaysian regulators to adopt a similar approach.

From the above arguments, this thesis takes the position that in Malaysia, it is not immoral or unethical to undertake HESC research and it can be controlled by restrictions and safeguards that facilitates moral, ethical and responsible research in that country. Provided important values are observed, there is unlikely to be moral harm caused to Malaysian society. The legacy is a responsible regulatory framework, for the benefit of present to future generations of Malaysians.

## **1.6 TO REGULATE HESC RESEARCH OR NOT?**

While this thesis aims to explore appropriate models of regulation for the Malaysian government to adopt to regulate HESC research, a preliminary inquiry is whether it is essential or even desirable to regulate HESC research at all. It might be argued that in Malaysia, it is preferable to adopt minimum regulation or to leave the research as totally unregulated as this facilitates free, unfettered and uninhibited research for the scientific community in the country. However, there are persuasive insights offered by eminent people in favour of adopting regulation, as explored below.

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<sup>88</sup> See Chapter 4.6.1 of this thesis

<sup>89</sup> Lockhart Report at 141

<sup>90</sup> See Chapter 5 of this thesis

<sup>91</sup> See Chapter 5.6 of this thesis

Michael Kirby makes a compelling argument in favour of regulation, particularly for contentious areas of research. He gives the example of human reproductive cloning where he asserts that ‘for the law to say nothing about the reproductive cloning of human beings is to give green light to experiments in that technology’.<sup>92</sup> He further explains that ‘nothing then exists to restrain [scientists] except for their own ethical principles, any institutional ethics clearance requirement, the availability of funding and their prospects of a market [and their religious convictions]’.<sup>93</sup> Thus where there is no regulation to prohibit or regulate an activity, scientists may decide to pursue controversial experiments out of simple interest and sheer curiosity. Kirby asserts that while ‘proponents of technological innovation have often favoured containment of law and a libertarian approach to development of technology, yet most lawyers recognise that there are limits’. He warns that the ‘absence of regulation will mean that the society has effectively made a decision to permit the technological advances to occur without impediment’. He stresses that ‘limits must be clearly expressed and upheld in an effective way’.<sup>94</sup>

Francis Fukuyama also argues that it is essential to regulate biotechnology.<sup>95</sup> He expresses concerns that unregulated biotechnology poses an insidious threat to society’s way of life and compromises human dignity.<sup>96</sup> He explains that:

the people in Brave New World may be healthy and happy, but they have ceased to be human beings. They no longer struggle, aspire, love, feel pain, make difficult choices, have families or do any of the things that we traditionally associate with being human. They no longer have the characteristics that give us human dignity.<sup>97</sup>

He adds there is a ‘fear that, in the end, biotechnology will cause us in some way to lose our humanity, that is some essential quality that has always underpinned their sense of who we are and where we are going’.<sup>98</sup>

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<sup>92</sup> Michael Kirby is a retired High Court judge. Kirby M ‘New Frontier’ in Brownsword R & Yeung K (eds), *Regulating Technologies*, Hart Publishing, Oxford & Portland, 2008, 367-388 at 375

<sup>93</sup> Kirby M, ‘New Frontier’ at 376

<sup>94</sup> Ibid at 382

<sup>95</sup> Francis Fukuyama is a political theorist. Fukuyama F, *Our Posthuman Future* Picador, New York, 2002

<sup>96</sup> Fukuyama explained that on one extreme of the continuum is nuclear technology which is extremely dangerous and on the other extreme is information technology (IT) which is relatively benign. Biotechnology lies in between the two extremes.

<sup>97</sup> Fukuyama F, *Our Posthuman Future* at 6

<sup>98</sup> Ibid at 101



In a similar vein, Professor Roger Brownsword supports the need for regulation, saying:

no regulation is hardly a serious option and there is surely little virtue in leaving eugenics to the play of subjective preference and the market ... if we accept the deeper implications of a liberal eugenics, such an abdication of regulatory responsibility is likely to have highly corrosive consequences ... the dilemmas associated with the regulation of human genetics must be confronted.<sup>99</sup>

Regulation of scientific research is not a new subject. In the context of biotechnology,<sup>100</sup> nations are enacting specific regulatory instruments to regulate controversial areas of research. In Australia, for example, the *Gene Technology Act 2000* (Cth) was passed to regulate research on genetically modified organisms (GMOs), the aim is to protect the health and safety of people and to protect the environment.

Legislation is not the only form of regulation. There is, for instance, soft law in the form of guidelines, an approach adopted for the regulation of research in Malaysia.<sup>101</sup> This thesis examines whether Malaysia should move to the next level by introducing legislation to regulate HESC research in future. In Australia, the decision has already been taken to pass legislation to regulate research involving human embryos. This is primarily because legislation promotes certainty and clarifies what is permissible for scientists. To quote a report examining the regulatory options for stem cell research and human cloning (Andrews Report): 'We owe it to the scientists to try and clarify, through legislation, those circumstances in which procedures may be acceptable ... and those cases in which a line may be drawn ...'<sup>102</sup>

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<sup>99</sup> Brownsword R, 'Regulating Human Genetics: New Dilemma for New Millennium' 2004 12 *Medical Law Review* 14-39 at 15

<sup>100</sup> Biotechnology is described as using living things, including plants and animals, to create products or to perform tasks for human beings. Over time, biotechnology has formed the basis of learning about human diseases and the development of medical treatments. It has led the way to a new era in health care with the development of improved methods for detecting, preventing and treating diseases. These include the development of new diagnostic and therapeutic tools, DNA profiling, cloning and stem cells

<sup>101</sup> See Chapter 8.3 of this thesis

<sup>102</sup> See 57-58 of Andrews Report where the committee reported that they agreed with Professor Donald Chalmers' view to introduce legislation

Therefore it is argued that in Malaysia, passing legislation to regulate HESC research will provide greater likelihood of clear parameters, scope and legal protections to scientists and ensures transparency and accountability as evident in the Australian regulatory regime (see chapters 4 to 6 in this thesis).

## **1.7 RESEARCH QUESTIONS AND AN OVERVIEW OF THE THESIS**

In developing a proposal for an effective regulatory framework to govern HESC research in Malaysia, this thesis poses the following research questions.

1) What are the ethical issues surrounding HESC research generally and specifically in Malaysia? Parts of this chapter have already addressed this research question by analysing the moral status of a human embryo and the ethical dilemmas this issue raises in 1.2 and 1.3. This chapter has also explored the various arguments in favour of as well against HESC research generally and in Malaysia in 1.4. The position this thesis takes and the reasons for so doing are presented in 1.5.

2) Why is HESC research considered to be important and what is the medical promise of the research? Are there alternatives to using human embryos in stem cell research? As it is essential to explore scientific facts before discussing the regulation of the research, Chapter 2 explores the biological and scientific bases of the science of HESC research and addresses this second research question. Its medical promise is evaluated with reference to various reports in reputable science journals. The following scientific facts are explained: the different types of stem cells; the sources of HESCs; the therapeutic cloning process; the medical promise of stem cells in the treatment of diseases or in the creation of new organs; and the development into clinical application and actual therapy. This chapter also explores the biological definition of a human embryo. As the science of stem cell is progressing, recent scientific breakthroughs are explained and explored, particularly the emergence of several types of stem cell alternatives that do not require the destruction of embryos. The use of induced pluripotent stem cells (IPS) is a particularly important breakthrough. Another innovative scientific development, the creation of human-animal embryos called cybrids, where animal eggs are used instead of human eggs, is also explained and explored.

3) What are the challenges in regulating HESC research and how are they addressed generally and specifically in Malaysia? Chapter 3 explores the theories of regulation, the challenges in regulating new technologies and the possible ways of addressing these challenges. Four regulatory challenges are specifically focused on: regulatory legitimacy, regulatory effectiveness, regulatory connection and regulatory cosmopolitanism. The chapter evaluates theories of responsive regulation to assist in the design an effective regulatory model for adoption in Malaysia.

4) What is the regulatory framework in other country where extensive HESC research is conducted? The thesis compares and contrasts the regulation of HESC research in other jurisdictions where extensive HESC research is conducted that could serve as useful models for Malaysia. The Australian position is evaluated in great detail because its framework for regulation of the research is highly developed.<sup>103</sup> Chapters 4, 5 and 6 address this research question, namely a comparative assessment of the regulatory framework in Australia, one that has evolved and developed since the ART days in the 1980s. Chapter 4 examines the extent to which the regulatory position in Australia achieves regulatory legitimacy. Chapter 5 examines the extent to which its regulatory framework maintains regulatory connection. Chapter 6 assesses the Australian licensing system, including its operations and the role of the inspectors in monitoring law compliance, and examines the extent its regulatory regime achieves regulatory effectiveness. This critical analysis of the Australian regulatory system for research involving human, embryo which has developed and evolved over a number of years, will offer important and useful insights for Malaysian regulators.

5) In multi-religious Malaysia, what are the various religious perspectives on the ethics and morality of HESC research? The thesis explores difficult theological questions of the main religions of the nation. It compares and contrasts the different religious interpretations leading to religious positions held on HESC research, if any. Chapter 7 explores various religious perspectives which inform HESC research in multi-religious Malaysia, and the challenge of achieving regulatory legitimacy in the country. The interpretation of key scriptural texts like the Quran and other faiths

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<sup>103</sup> The Australian regulation on research involving human embryos is evaluated in Chapters 4, 5 and 6 of this thesis

are discussed. The chapter addresses this research question, where philosophical issues are discussed with the exploration of when life begins and the concept of ensoulment. Some of these issues were raised in interviews with representatives of various faiths in Malaysia. In addition, these interviews clarified the less vehement opposition to HESC research in Malaysia when compared with other countries like the USA and Australia.

6) What HESC research is being conducted in Malaysia and how is the research regulated? What are the strengths and weaknesses of the existing regulation, if any? Chapter 8 investigates the current status of the research being conducted in Malaysia. In addition, it investigates whether there is in existence a regulatory framework governing HESC research and if there is, it evaluates the effectiveness of the existing framework. Part of the empirical evidence discussed in this chapter is derived from interviews with the Malaysian governmental authorities.

7) In the context of HESC research, how does the theory of regulation apply in a multi-religious, developing nation like Malaysia? The analysis of leading academic regulation theories leads to the recommendation of the adoption of a highly effective model designed to regulate and facilitate responsible HESC research in Malaysia is explored in Chapter 3 of this thesis. Chapter 9 draws the conclusion together with the research findings in order to directly address the research questions and summarise the key issues. The recommended regulatory model for the Malaysian government to adopt in regulating HESC research is unveiled.

## **1.8 RESEARCH METHODOLOGY**

The research for this thesis can be broken down into three critical stages. First, an extensive review of primary sources has been undertaken. These sources include scientific journal articles, official reports (scientific and legal), religious texts including the Bible and the Quran, primary legislation, delegated legislation, bills, Constitution, Hansard/ parliamentary debates, cases, international treaties, guidelines and codes..

Secondly, an extensive review of various secondary sources has also been undertaken. These sources include books and journal articles, internet sources (for instance, online articles and Bionews), respectable newspapers (for instance, the Australian, BBC and the Guardian), magazines (for instance, Time, Newsweek, the New Yorker) and seminar presentations.

The third empirical research component of this thesis comprised face-to-face interviews. The interviews were conducted with ministries, regulatory authorities, government agencies, legislative review committee, scientists, doctors, academics and representatives of religious groups. The purpose of these interviews was to obtain new data including the opinion and interpretations of eminent and respected people in their respective fields. This aspect of the thesis received ethical approval from the Tasmanian Social Science Human Research Ethics Committee in 2007.<sup>104</sup> Upon receiving the approval, the process of recruitment of interviewees began.<sup>105</sup> Arrangements for face-to-face interviews were made months in advance via email and telephone calls. Upon receipt of consent, the interview questions and information sheet were sent to the participants via email, in advance of the interview. Interviews were conducted in different cities in three countries; Kuala Lumpur, Petaling Jaya, Putrajaya, Malaysia; in Melbourne, Sydney and Canberra, Australia; and in London and Sheffield, UK. All interviews were audio-recorded with consent. All interviewees signed a consent form. The duration of each interview varied, but was usually between one hour and one and half hours each. After the interviews were concluded, transcripts of the interviews were typed and sent to the interviewees for their review and approval.

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<sup>104</sup> Ethics reference no H9729

<sup>105</sup> The organisations and people who have agreed to be interviewed are listed in Appendix 1 of this thesis

## **2: WHY IS IT NECESSARY TO USE HUMAN EMBRYOS FOR STEM CELL RESEARCH?: THE SCIENCE**

### **2.1 INTRODUCTION**

This chapter explores the developing science of stem cell technology with the focus on human embryonic stem cells (HESC). Understanding and appreciating the technicalities of the science will support the thesis' argument that it is important to pursue stem cell research in general and, in particular, HESC research. This is despite the controversies surrounding HESC research, the availability of adult stem cells as a substitute, and the emergence of many recent developments known as stem cell alternatives which do not involve the creation and destruction of embryos. The chapter also explains and argues in favour of the creation of cybrids despite the controversial nature of this technology.

Before embarking on any discussion of the regulation of stem cell research, it is necessary to give an account of the science to understand the ethical issues associated with the science.<sup>1</sup> The chapter assesses the medical potential and importance of stem cells as tools for research. This chapter does not aim to make a novel contribution to the scientific debate but, rather to serve as a scientific background for later chapters through an account of the technicalities and complexities of the science. This account is made with reference to explanatory figures and photographs. A glossary is included in Appendix 2.

The chapter explores the origins of stem cell research, tracing the early discovery of stem cells up to the recent scientific breakthroughs. A distinction is drawn between the different types of stem cells, particularly adult stem cells and HESCs, and the

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<sup>1</sup> The cumulative sources of information include Nature, Science, National Academies, Proceedings of National Academy of Science (PNAS), New England Journal of Medicine, Cell and Cell Research. This chapter refers substantially to *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies*, National Academies Press, Washington DC, 2006

advantages and disadvantages of the use of each type as research tool is evaluated. As the major argument against HESC research is that it involves the destruction of embryos, it is crucial to analyse the biological and legal definitions of human embryo.<sup>2</sup>

An important distinction must be drawn between research and therapy. This chapter provides an explanation of the research, clinical applications and includes an assessment of the translation from stem cell research to stem cell trials and eventual therapies.

The chapter also examines the recent alternative methods to using human embryos in stem cell research, particularly induced pluripotent stem cells (IPS cells). It queries whether these alternatives might replace HESCs. An attempt is made to assess the viability of pursuing each of these alternative methods. Finally, a controversial scientific development, the creation of cytoplasmic hybrids/ cybrids, is explored. As cybrids are created using animal eggs, they could help to address the problem of shortage of human eggs, a vital ingredient in HESC research. However, mixing of human and animal genetic material is highly contentious.

## 2.2 WHAT ARE STEM CELLS?<sup>3</sup>

Stem cells are master cells that have the ability to produce different cells and tissues. As blank slates/ immature cells, they have yet to become specialised. Unlike fully mature cells, stem cells have a variety of potential futures. They have the unique capacity to develop into specialised/differentiated cells that carry out the specific functions of the body. This means they can become any type of cell to form skin, bones, organs and other body parts.

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<sup>2</sup> Findlay JK et al 'Human Embryo: A Biological Definition' (2007) 22 *Human Reproduction* 905-911. See also

[http://www.nhmrc.gov.au/\\_files\\_nhmrc/file/research/embryos/reports/humanembryo.pdf](http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf) (10 May 2010). The UK's Report of the Committee of Inquiry into Human Fertilisation and Embryology (Warnock Report) (1984) also explains the early human development at 58-60

<sup>3</sup> This section of this chapter refers substantially to *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies*, National Academies Press, Washington DC, 2006, 3-11

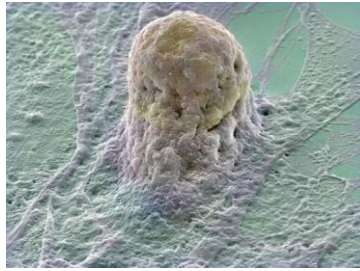


Figure 1: An image of stem cells (Reprinted with permission from Wellcome Images, <http://www.wellcome.ac.uk/en/bia/gallery.html?image=13>)

The human body is made up of over 200 different types of cells.<sup>4</sup> Serving as a repair system for the body, stem cells can divide to replenish other cells.<sup>5</sup> When a cell divides, each new cell has the potential to either remain a stem cell or to become another type of cell with a more specialised function.<sup>6</sup> This unique characteristic makes them appealing for scientists seeking to create new cells to replace lost or damaged cells, and in the past few decades, scientists have gradually deciphered the processes by which unspecialised stem cells become specialised cell types in the body.<sup>7</sup>

Stem cells are found in all humans<sup>8</sup> and are important research tools for use in the study of normal and abnormal human embryo development, discovering new genes, testing drugs and other substances that cause birth defects. They are a renewable source of cells for tissue transplantation, cell replacement and gene therapies. They are touted as being useful in research and treatment of such diseases as Parkinson's, Alzheimer's, stroke and other neurodegenerative diseases<sup>9</sup> and diabetes.<sup>10</sup>

## 2.3 THE DISCOVERY STEM CELLS<sup>11</sup>

For centuries, scientists have known that some animals,- including starfish, newt, salamander and lizards- have the ability to regenerate missing parts of their bodies.

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<sup>4</sup> See *Understanding Stem Cells* at 3

<sup>5</sup> Ibid at 2

<sup>6</sup> Ibid

<sup>7</sup> Ibid at 3

<sup>8</sup> Ibid at 4

<sup>9</sup> Linvall O & Kokaia Z 'Progress Stem Cells for the Treatment of Neurological Disorders' (2006) *Nature* 1094-1096

<sup>10</sup> *Understanding Stem Cells* at 16

<sup>11</sup> See *Understanding Stem Cells* at 4. See Appendix 3 of this thesis for the table of cloning timeline from 1838 until present day



Humans share this ability with these animals to some limited extent;<sup>12</sup> while a missing leg or a finger cannot be replaced, human bodies constantly regenerate blood, skin and other tissues.

In the 1950s, experiments with bone marrow established the existence of stem cells in human bodies, leading to the development of bone marrow transplantation, a therapy now widely used in medicine.<sup>13</sup> This discovery raised hope that doctors could regenerate damaged tissue with a new supply of healthy cells by drawing in the capability of stem cells to create many of the body's specialised cells. As a consequence, researchers were motivated to attempt to identify similar cells within the embryo. Early studies of human development proved that cells from the embryo have the capabilities of producing every cell type in the human body. In the 1980s scientists were able to extract embryonic stem cells from mice.<sup>14</sup> In 1998 a team led by Dr James Thomson of University of Wisconsin was the first to isolate HESC.<sup>15</sup> Human stem cells lines were derived from blastocysts<sup>16</sup> which had been cultured from donated excess/ spare IVF embryos.

## **2.4 CELL CULTURE, CELL LINES AND DIFFERENTIATION<sup>17</sup>**

The term 'cell culture' refers to the growth and maintenance of cells in a controlled environment outside a living organism. 'A successful stem cell culture is one that keeps the cells healthy, dividing and unspecialised' and 'culturing of stem cells is the first step in establishing a stem cell line', that is, 'a propagating collection of genetically identical cells.'<sup>18</sup> Establishing stem cell lines is important as they can provide a long-term supply of multiplying cells which can then be distributed and shared among researchers. After scientists establish a stable stem cell line, they can then begin to coax the stem cells to differentiate into specialised cell types. Stem cells may provide scientists with clues on how to make these cells differentiate in a

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<sup>12</sup> *Understanding Stem Cells* at 2

<sup>13</sup> *Ibid*

<sup>14</sup> Evans MJ and Kaufmann M, 'Establishment and Culture of Pluripotential cells from mouse embryos' (1981) 292 *Nature* 154 -156, Martin GR 'Isolation of a Pluripotent Cell Line from Early Mouse Embryos Cultures in Medium Condition by Teratocarcinoma Stem Cells' (1981) 78 *Proceedings of the National Academy of Science* 7634-7638

<sup>15</sup> Thomson J et al, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145-1147

<sup>16</sup> For explanation on blastocyst, see 2.5.2 of this chapter

<sup>17</sup> This technical section relies heavily on *Understanding Stem Cells* at 10

<sup>18</sup> *Understanding Stem Cells* at 10

culture dish. For instance, in bone marrow where blood stem cells reside, the blood cells send physical and chemical signals that tell the blood stem cells when to differentiate. Scientists are just beginning to understand these signals. They have developed ways to mimic the natural processes in cell cultures and the technology involves adding proteins to the cell culture and introducing specific genes into the stem cells.

## 2.5 TYPES OF STEM CELLS<sup>19</sup>

It is important to appreciate the different types of stem cells, particularly the distinction between ‘adult stem cells’ and ‘embryonic stem cells’. There are no serious ethical or legal issues with adult stem cells since patients either use their own stem cells or they are donated by donors, as in a leukaemia patient receiving bone marrow transplantation from his/ her sibling(s).

However, HESC research, the focus of this thesis, is highly controversial because extracting the stem cells destroys the embryo and thus destroys its potential for life.

### 2.5.1 ADULT STEM CELLS/ NON EMBRYONIC STEM CELLS

While adult stem cells are important for research and therapeutic purposes, as they are not the main topic for consideration, they will only be considered briefly in this section as a matter of comparison with HESCs.

Adult stem cells are found in various tissues in fully developed humans, from babies to adults. They have been found in organs that need a constant supply of cells such as blood and lining of the gut.<sup>20</sup> They have also been found in surprising places like the brain, which is not known to readily replenish its cells.<sup>21</sup> Other organs where they have been found are skin,<sup>22</sup> bone marrow,<sup>23</sup> nose<sup>24</sup> and

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<sup>19</sup> Ibid at 4

<sup>20</sup> *Understanding Stem Cells* at 8

<sup>21</sup> Ibid

<sup>22</sup> Li J et al, ‘Mice cloned from Skin Cells’ (2007) *Proceedings of the National Academy of Sciences of the United States of America* 2738-2743

<sup>23</sup> Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, Report from the Chief Medical Officer’s Expert Group (2000) at 19

<sup>24</sup> Australian Scientists Grow Adult Stem Cells from Nose’ <http://www.stemcellnews.com/articles/stem-cells-adult-from-nose.htm> (2005) (21 April 2009)

testicles.<sup>25</sup> It is believed they could be found in other organs as well. Searching for adult stem cells is not a simple process, as they tend to be inconspicuous in shape and size, hidden deep in tissues and present in low numbers.<sup>26</sup> Their identification has been described as like ‘finding a needle in a haystack.’<sup>27</sup> Each adult stem cell displays an array of proteins on its surface and scientists use the surface proteins as markers or molecular IDs. However, not all stem cells can be identified in this manner, and scientists have not yet identified markers for all stem cell types. Stem cells can also be identified by observing their behaviour in the laboratory.

Adult stem cells are multipotent and not pluripotent. This means they can only give rise to some types of cells and are not as flexible as pluripotent stem cells. For example, blood stem cells only give rise to other types of blood cells and nerve stem cells can only make various types of brain cells. However, research suggests that some adult stem cells, such as those from the testicles, might be more flexible than previously thought and may be made to produce a wider variety of cell types.<sup>28</sup>

Recent studies have shown that adult stem cells can also be derived from foetal tissue such as umbilical cord blood, amniotic fluid<sup>29</sup> and placenta. As a result of finding adult stem cells in umbilical cords, there is now a trend to bank newborn umbilical cords blood for future stem cell treatment. It has been estimated that internationally, public and private banks store an estimated one million units of umbilical cord blood containing stem cells that could theoretically match many patients with potential use for regeneration.<sup>30</sup> In addition, scientists at Kingston University, London have found a way of multiplying new cells using NASA technology called bioreactor to ensure there are enough stem cells to repair tissue damage caused by injury or disease.<sup>31</sup>

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<sup>25</sup> Skutella T et al, ‘Generation of Pluripotent Stem Cells from Adult Human Testis’ (2008) 456 *Nature* 344-349

<sup>26</sup> *Understanding Stem Cells* at 9

<sup>27</sup> *Ibid*

<sup>28</sup> ‘Testes Stem Cells Can Change into Other Body Tissues’ (2009) <http://www.sciencedaily.com/releases/2009/01/090105154256.htm> (11 June 2010)

<sup>29</sup> Trounson A, ‘A Fluid Means of Stem Cell Generation’ 25 *Nature Biotechnology* 62-63

<sup>30</sup> McGuckin CP & Forraz N et al, ‘Production of Stem Cells with Embryonic from Human Umbilical Cord Blood’ (2005) 38 *Cell Proliferation* 245-255

<sup>31</sup> *Ibid*

A team at the University of Pittsburgh reported the discovery that cells in human placental tissue have the same ability as embryonic stem cells to develop into any type of cell.<sup>32</sup> These cells, known as amniotic epithelial cells, are found in a part of the placenta called the amnion, or the outer membrane of the amniotic sac. They are described as having strikingly similar characteristics to embryonic stem cells. Placentas are usually destroyed following birth. Like umbilical cord blood, parents could choose to store their child's amniotic epithelial cells in the event they may be needed. However, a major limitation with amniotic epithelial cells is that they cannot be grown indefinitely, possibly due to the fact they do not express an enzyme called telomerase, which is important for normal DNA and chromosome replication and, by extension, cell division.

There have also been some significant advancements in the use of adult stem cells recently. Two examples illustrate this point. First, 'scaffolds' have been used to construct new body parts, for instance, a trachea. In this research, adult stem cells are combined with biomaterial scaffolds for tissue engineering applications, that is, as means of replacing diseased or damaged tissues. There is some evidence to suggest that this technique can restore functionality.<sup>33</sup> This finding suggests that adult stem cells combined with biomaterials might have broader applicability in the reconstruction of non-functional body parts.

Secondly, it seems that it may be possible to restore sight using adult stem cells. In one experiment, bone marrow stem cells were transplanted into damaged retinas.<sup>34</sup> The result of this research suggests that bone marrow cells have the capacity to differentiate into retinal cells and that injections of these stem cells may help repair damage to the retina.

It is critical for scientists to continue conducting adult stem cell research. These cells have been used in research for decades with the early experiments with bone

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<sup>32</sup> 'Discarded Placentas Deliver Researchers Promising Cells Similar to Embryonic Stem Cells' (2005) <http://www.bio-medicine.org/biology-news/Discarded-placenta-deliver-researchers-promising-cells-similar-to-embryonic-stem-cells-1575-3/> (21 April 2009)

<sup>33</sup> Macciarini et al, 'Clinical Transplantation of a Tissue-Engineered Airway' (2008) *Lancet* 2023-2030

<sup>34</sup> Tomita et al, 'Bone Marrow-Derived Stem Cells Can Differentiate into Retinal Cells in Injured Rat Retina' (2002) *Stem Cells* 279-283

marrow determining the presence of stem cells in human bodies that has led to the development of bone marrow transplantation, a medical treatment widely used in medicine at present day. Also, with the recent significant developments in the use of adult stem cells mentioned above, it is imperative for scientists to continue pursuing adult stem cell research along with HESC research.

### **2.5.2 HUMAN EMBRYONIC STEM CELLS (HESCs)**

HESCs are stem cells derived from human embryos. It is stressed that these embryos are at an early stage in development when they are destroyed for the extraction of stem cells.

The embryo may be a better source of stem cells for research than the adult because HESCs have two distinct characteristics. First, they are pluripotent; this means that HESCs are capable of producing most cell types in the body. They can give rise to cells that form all three embryonic germ layers, the ectoderm, mesoderm and endoderm. Ectoderm gives rise to brain, spinal cord, nerve cells, hair, skin, teeth, sensory cells of eye, ears, nose and mouth and pigment cells. Mesoderm gives rise to muscles, blood, blood vessels, connective tissues and the heart. Endoderm gives rise to the gut, pancreas, stomach, liver, lungs, bladder and germ cells, eggs or sperm.

Secondly, HESCs can be grown in laboratory culture for long periods without losing their pluripotency, and are capable of self-renewal. The cells can divide to reproduce themselves for a prolonged period of time without differentiating. In comparison, adult stem cells are present only in minute quantities in the body and they are difficult to isolate successfully and, thus far, it has been nearly impossible to grow them outside the body.

HESCs are derived from two sources: (a) spare/excess in vitro fertilisation embryos; and (b) cloned embryos.

#### *Excess/ surplus in vitro fertilisation embryos*

A major source of HESCs for use in medical research is embryos stored in vitro fertilisation (IVF) clinics, specifically in the freezers of the clinics. The IVF process

requires the retrieval of a woman's eggs through a surgical procedure after undergoing an intensive regimen of fertility drugs which stimulate her ovaries to produce multiple mature eggs (see Figure 2). Typically, doctors fertilise all of the eggs in order to maximise the chance of producing a viable blastocyst that could be implanted in the womb. Because not all the fertilised eggs are implanted, this has resulted in a large bank of excess blastocysts stored in freezers. After a certain date in storage in freezers, these embryos are destroyed.<sup>35</sup> Because these embryos are destined to die, it is argued that research involving stem cells from excess IVF embryos is not as controversial as research involving embryos created for the specific purpose of harvesting HESCs. However, some sections of society continue to see this as ethically problematic as it still involves the destruction of embryos.

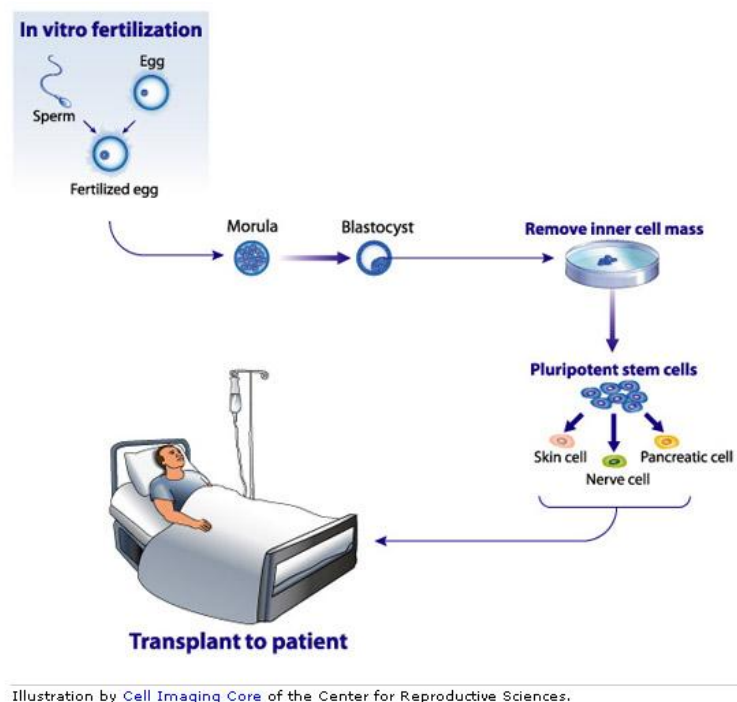


Illustration by [Cell Imaging Core](#) of the Center for Reproductive Sciences.

Figure 2: Using excess IVF embryos (reprinted with permission from University of Kansas medical center, <http://www.kumc.edu/stemcell/images.html>)

The IVF technique could also be used to deliberately produce embryos specifically for research purposes. This would facilitate the isolation of stem cells with specific genetic traits necessary for the study of particular diseases. For example, to study the origins of an inherited disease, stem cells made from egg and sperm donors who

<sup>35</sup> See Chapter 1.4.1 of this thesis about the position in Victoria

have this disease, could be used. However, this is ethically problematic because it involves deliberate creation and destruction of an embryo.

*Somatic cell nuclear transfer/ therapeutic cloning*<sup>36</sup>

The other source of ESCs is the deliberate creation of embryos through the process of therapeutic cloning, what is scientifically known as ‘somatic cell nuclear transfer’ (SCNT).

Before explaining the process of somatic cell nuclear transfer (SCNT), it is important to explain cloning and the process of its production. To clone is to copy. It comes from the Greek word *klon*, which means twig.<sup>37</sup> Reproduction by cloning occurs in plants like potatoes, in insects like honeybees and wasps, and in amphibians.<sup>38</sup> An identical twin is a natural clone. All cells in human bodies are clones with the exception of sperm and egg cells. The process of cloning goes on continually, for instance, skin cells and cells that line the gut turn over rapidly and genetically identical copies, clones, are produced to replace the ones that wear out.

Cloning is a method of making copies of the genetic codes of a living organism. This is illustrated in the cloning of the first mammal, Dolly, the sheep (see Figure 3).<sup>39</sup> The cloning process is as follows. The nucleus of an egg cell is removed and a nucleus from the person to be cloned is inserted into the cell. A chemical trigger starts the egg growing and dividing as if it has been fertilised by a sperm except that instead of having chromosomes from two people, it has chromosomes from one. In theory, this cell behaves precisely like an embryo, it divides and it develops. The embryo could be implanted into a surrogate mother’s womb and nine months later, the baby is born. This process is known as reproductive cloning, and at present, is

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<sup>36</sup> The term CNR (cell nuclear replacement) was used in the earlier science literature

<sup>37</sup> Diamandopoulos AA & Goudas PC, ‘Cloning’s Not a New Idea: the Greeks Had a Word for it Centuries Ago’ (2000) 408 *Nature* 905

<sup>38</sup> Wickware P, ‘History and Techniques of Cloning’ in McGee G & Caplan A (eds), *The Human Cloning Debate*, 4<sup>th</sup> Edition, Berkeley Hills Books, Berkeley, 2004, 13-35 at 15

<sup>39</sup> This experiment was conducted by a Scottish scientist, Professor Ian Wilmut in 1997. The cloned sheep was named after the country singer, Dolly Parton. The cells were taken from the mammary glands of the sheep

prohibited in many countries because it is not only contentious ethically but also unsafe.<sup>40</sup>

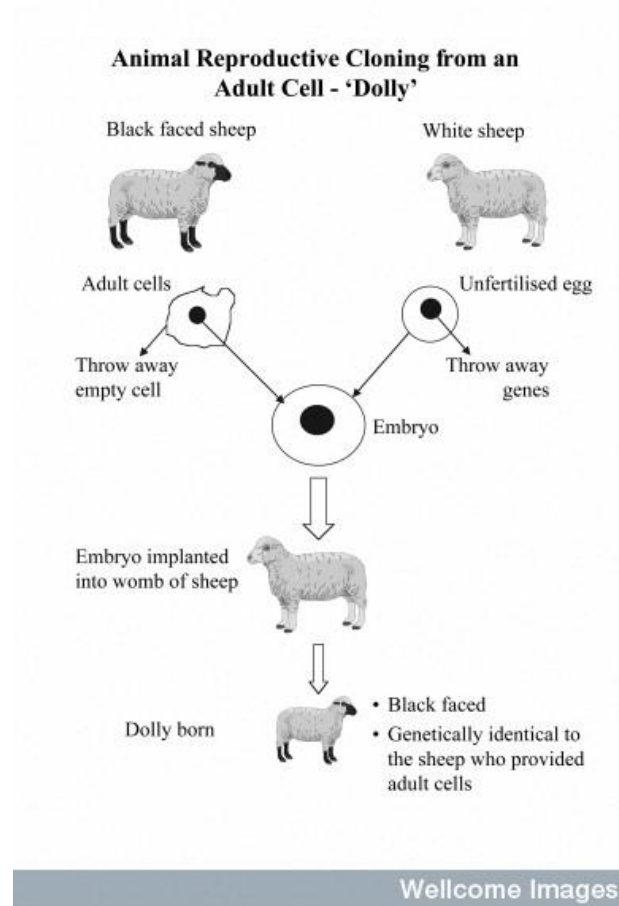


Figure 3: The cloning process (reprinted with permission from Wellcome Images, <http://images.wellcome.ac.uk/>)

Therapeutic cloning involves the process of forming a cloned human embryo, for the purpose of using it in research or for extracting its stem cells, without any intention of implanting the embryo into a woman's womb for further development (see Figure 4). The process is similar to that used to make Dolly, the difference being that instead of implanting the embryo into a womb, it is destroyed in order to extract stem cells from it. This happens at around four to seven days after fertilisation where it forms a blastocyst.

<sup>40</sup> This is reflected in Article 11 of the UNESCO Universal Declaration on the Human Genome and Human Rights 1997 which states: 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected'



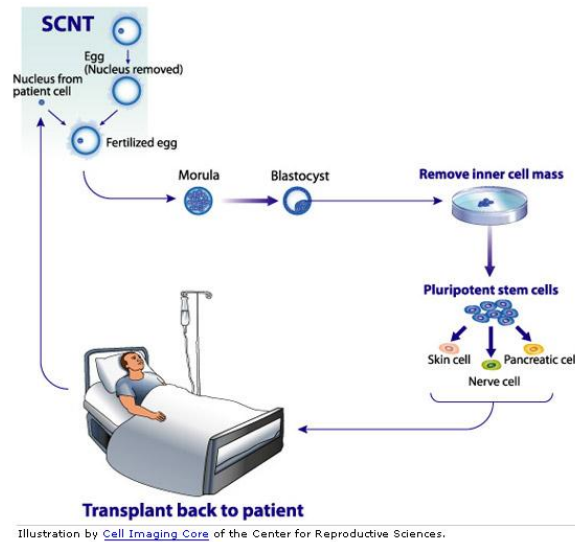


Figure 4: SCNT process (reprinted with permission from University of Kansas medical center, <http://www.kumc.edu/stemcell/images.html>)

The blastocyst is a hollow sphere which consists of about 100 to 200 cells (see Figures 5 and 6). Human blastocysts are smaller than the full stop/period at the end of a sentence (see appendix 4 of this thesis).<sup>41</sup> They contain all the material necessary for the development of a complete human being. The interior of a blastocyst contains inner cell mass, which is composed of 30-34 cells that are pluripotent. When scientists wish to extract HESCs, they disassemble the blastocysts and place the inner cell mass in a culture dish with a nutrient rich liquid.<sup>42</sup> At certain stages of development, they can be teased into becoming specific kinds of cells say, kidney or heart or brain<sup>43</sup> by adding growth factors such as protein. Theoretically, these replacement tissues will be the perfect match for the person with the disease, as the stem cells created are copies or clones of the original adult cell.

<sup>41</sup> It is also described as a ball of cells. In normal development, the blastocyst will implant in the wall of the uterus to become the embryo and continuing developing into a mature organism. Its outer cells would begin to form the placenta and the inner cell mass would begin to differentiate into the progressively more specialised cell types of the body. See appendix Four that provides a picture that indicates the size of a blastocyst

<sup>42</sup> This is known as isolation and culturing of stem cells

<sup>43</sup> This is known as differentiation into specialised cell types

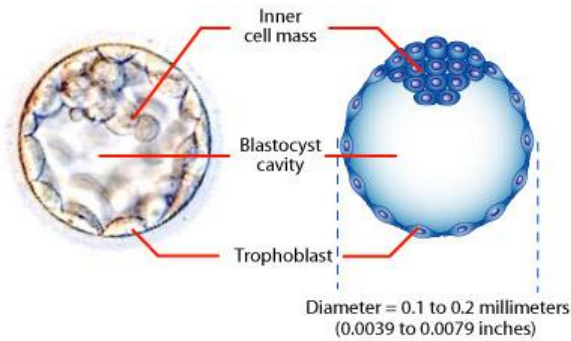


Illustration by [Cell Imaging Core](#) of the Center for Reproductive Sciences.

Figure 5: An image of a blastocyst (reprinted with permission from University of Kansas medical center, <http://www.kumc.edu/stemcell/images.html>)

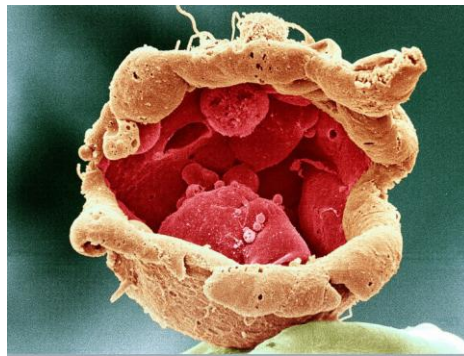


Figure 6: Colour-enhanced electron microscope image of a human embryo at the blastocyst stage opened to reveal the inner cell mass. (Reprinted with permission from Wellcome Images, <http://images.wellcome.ac.uk/>)

There are important reasons for conducting SCNT research. First, the research enables scientists to study the development and progression of diseases by creating stem cells containing the genes responsible for certain disorders in the human body.

Secondly, cloned cells are likely to be more useful in the medical treatments of diseases than ordinary HESCs due to a lower risk of tissue rejection. The ESCs created by SCNT would be genetically matched to the patient needing a transplant, making it far less likely that the patient's body would reject the new cells than it would with traditional tissue transplant procedures. As it is the patient's own DNA, his/her body would recognise it and he/she has a perfect match.

Thirdly, scientists hope to be able to grow organs that enable doctors to transplant tissue and organ cells. Currently there is lack of organ donors, resulting in long

waiting lists for patients needing organ transplantation. In the future, SCNT technology may allow organs and tissues to be grown as and when they are needed. However, it is acknowledged there are potential safety and technical issues with the SCNT process. There is the risk of creating teratoma, that is, tumours, from implanting undifferentiated stem cells. It has been suggested that cells produced through this process may not give rise to as wide a range of normal tissues as these cells may have various functional defects.<sup>44</sup>

Reproductive cloning carried out by SCNT is fraught with difficulties. Differentiated cells obtained from adult cells may age differently from normal cells. For instance, Dolly had been shown to have cells that appear older than her age.<sup>45</sup> The success of the cloned sheep was achieved after 277 attempts.<sup>46</sup> The failures are often seen from the earliest development and are associated with very serious abnormalities that may not become evident until some time after birth. There have been similar failed attempts on other species and mutations could arise in the adult cell used.<sup>47</sup>

There are unknown implications of SCNT. Animals born from SCNT are not identical to the animal whose cell nucleus was used in the process. This is because they inherit mitochondrial DNA from the egg. The implications of this on the compatibility of tissue derived from the embryos created by SCNT are not known and potentially contentious.<sup>48</sup>

While there are risks and uncertainties about the SCNT process at present, it is still argued that it is an imperative to conduct this research because it is a vital tool for research purposes. It is noted that in 2009, the Geron trial in United States of America (USA) was approved by Food and Drug Administration (FDA) and in the

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<sup>44</sup> See *Stem Cell Research: Medical Progress with Responsibility* at 26

<sup>45</sup> Ibid. It was pointed out in the report that there is conflicting evidence; data that cloned cows suggests their cells have the characteristics of cells younger than those expected of the age of the animals

<sup>46</sup> Pennisi E & Williams N, 'Will Dolly Send In the Clones?' (1997) 275 *Science* 1415-1416. Dolly did not live till old age; she died at premature age six. She was euthanised due to progressive lung disease

<sup>47</sup> See 'History and Techniques of Cloning' at 28. It mentioned that many died prematurely; some were aborted, some were stillborn and some were euthanised

<sup>48</sup> See *Stem Cell Research: Medical Progress with Responsibility* at 23

following year, the company announced the enrolment of the first patient in the clinical trial of HESC derived oligodendrocyte progenitor cells (GRNOPC1).<sup>49</sup> This thesis takes the position that as more SCNT research is pursued by scientists around the world, the techniques of this research will improve and be perfected over time.<sup>50</sup>

### **2.5.3 EMBRYONIC STEM CELLS VERSUS ADULT STEM CELLS<sup>51</sup>**

Arguments on the relative value of embryonic and adult stem cell research have been at the core of ethical debates. It is frequently argued that only adult stem cell research should be pursued but not HESC research on the basis that adult stem cell research not only has its medical potential but also avoids serious ethical dilemma. Rather than evaluating the ethics of these arguments, this section aims to evaluate the scientific advantages and disadvantages of using these two types of stem cells in research.

First, HESCs are relatively easy to identify, isolate, maintain and grow in the laboratory. In comparison, adult stem cells are difficult to isolate as they are inconspicuous, hidden deep in tissues and are present only in low numbers.<sup>52</sup> In addition, adult stem cells are not found in all tissues. Second, HESCs are more flexible than adult stem cells. As they are pluripotent, they have the potential to produce very cell type in the human body. In comparison, adult stem cells are multipotent and produce limited number of cell types.

## **2.6 THE BIOLOGICAL DEFINITION OF A HUMAN EMBRYO**

As the crux of the argument raised against HESC research is that it involves the destruction of human embryos, a scientific understanding of a human embryo is essential to know when this destruction occurs. It is crucial, therefore to analyse the biological definition of human embryo. The National Health Medical Research

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<sup>49</sup> 'Geron Initiates Clinical Trial of Human Embryonic Stem Cell-Based Therapy' (2010) <http://www.geron.com/media/pressview.aspx?id=1229> (1 November 2011). However, it is noted that this trial has just ceased

<sup>50</sup> There is confidence in the hard work of scientists. As illustrated in 2.7.6 of this chapter, there is sufficient evidence of scientists around the world perfecting theirs and each other's techniques

<sup>51</sup> See *Understanding Stem Cells* at 8

<sup>52</sup> Ibid

Council (NHMRC), following a recommendation of the Lockhart Report, established a working party, to consider this issue. The working party produced a discussion paper (hereafter DP) entitled ‘Human Embryo-A Biological Definition’ based on a meeting of experts.<sup>53</sup> It is noted that the DP did not include the ethical and moral ramifications of emerging technologies as those issues are beyond the scope of the paper.<sup>54</sup>

The DP includes a helpful diagram that illustrates the stages of fertilisation where the sperm with male pronucleus meeting the egg with female pronucleus, and the two pronuclei are drawn together.<sup>55</sup> The membranes of the two pronuclei fuse and the chromosome of the sperm and egg are combined to form a zygote which is a genetically unique entity in day one. The first cleavage division occurs around day two or three, followed by the two-cell stage to four-cell stage to eight-cell stage and finally the formation of a morula. On days four to seven, a blastocyst is formed. On day 15, an embryo proper is formed. The primitive streak appears in the primary ectoderm and all subsequent embryonic and fetal tissue develops from this structure. This is an important stage, because: ‘the appearance of the primitive streak is the point at which the body plan begins to become established and signals the commencement of gastrulation’<sup>56</sup> and ‘this is the first developmental point at which a multi cellular structure is formed that will uniquely develop into the new individual encoded by the new genome.’<sup>57</sup>

The NHMRC working party identified two main schools of thoughts about the biological definition of an embryo, one being broad and the other more restricted. The broad definition sees that a conceptus is an embryo from the moment of its creation, e.g. fertilisation. The restricted definition sees that a conceptus should be referred to as an embryo only after gastrulation at which time the cells will give rise

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<sup>53</sup> Findlay JK et al ‘Human Embryo: A Biological Definition’ (2007) 22 *Human Reproduction* 905-911. See also National Health Medical Research Council, ‘Human Embryo’ - A Biological Definition (DP) (2006) at [http://www.nhmrc.gov.au/\\_files\\_nhmrc/file/research/embryos/reports/humanembryo.pdf](http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf) (10 May 2010)

<sup>54</sup> DP at 29

<sup>55</sup> See Figure 1 at 7 and 8 of DP

<sup>56</sup> Ibid at 10

<sup>57</sup> Ibid

to the future human being can be distinguished from those that form extraembryonic tissue including placenta, cord, membrane.’<sup>58</sup>

The working party suggested that the Australian public’s understanding of a human embryo is the broad definition, whereas the medical and scientific community have used the restricted definition of embryo. There has been no disagreement about the end point of the embryonic phase, that is, eight weeks after conception where a foetus is formed. However, the earlier boundary is harder to pinpoint, especially for embryos created by methods other than fertilisation of an egg with sperm such as SCNT technology. A number of researchers prefer the restricted definition.<sup>59</sup> The working party referred to explanations provided by textbook authors and suggested that the human embryo exists only from the time of gastrulation, which is approximately 16 days post-fertilisation. Prior to this time, the developing entity does not have distinct populations of human embryonic cells.<sup>60</sup> On this basis, the developing entity up to gastrulation should not be termed as an embryo:<sup>61</sup>

... the first 14-16 days of human development are concerned mainly with the elaboration with the conceptus of various extra-embryonic tissues and their discrete separation from a population of cells, the embryo, that will give rise exclusively to a single foetus. This 14-16 day period is therefore said to be the embryogenic phase of development, i.e., generating an embryo. Prior to this stage, the total product of fertilisation is properly called the conceptus (also called pre-embryo or pro-embryo).<sup>62</sup>

This view is supported by the so-called ‘twinning argument’ raised in a report of the President’s Council on Bioethics entitled Human Cloning and Human Dignity (President’s Council Report), based on the fact that in the first fourteen days after fertilisation, the embryo may split into two to be identical twins. It states:

First, it is still unclear in the initial fourteen-day period whether an embryo will develop into one or more human beings. The possibility for “twinning” is still present, suggesting that the earliest-stage embryo is either not yet an individual or is a being that is not confined to becoming only one individual. There are continuing philosophical debates about how to understand what

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<sup>58</sup> DP at 3-4

<sup>59</sup> Ibid at 4

<sup>60</sup> Definition by Johnson and Selwood in Johnson MH & Selwood L, ‘Nomenclature of Early Development in Mammals’ (1996) 8 *Reproduction, Fertility and Development* 759-764

<sup>61</sup> Definition by McLaren in McLaren AL, ‘Embryo Research’ (1986) 320 *Nature* 570, McLaren AL, ‘Why study Early Human Development?’ (1986) 109 *New Scientist* 49-52, McLaren AL, ‘Pre-embryos?’ (1987) 329 *Nature* 10

<sup>62</sup> Definition by Johnson and Everitt in Johnson MH & Everitt BJ, *Essential Reproduction*, 5<sup>th</sup> edition, Blackwell Science Ltd, Oxford, 2000

happens in twinning: for example, whether one individual embryo “clones” itself to produce a second, or an organism that resembles (but is not yet) an individual embryo divides into two truly individual beings. Nevertheless, the biological - and we believe moral-significance of the possibility for twinning is clear: after fourteen days (or after the primitive streak is formed), the being in question can no longer be anything but a single being- that is to say, no embryos after this stage, and thus no fetus or live-born baby, can replicate or divide to form another identical being. Before fourteen days, this possibility remains.<sup>63</sup>

The NHMRC working party also considered the critical question of whether the entities generated by emerging technologies including SCNT are considered as embryos.<sup>64</sup> These entities do not involve fertilisation by a male and female gamete and therefore may not be considered as embryos.<sup>65</sup> In the DP, a table explains that in SCNT there is no fertilisation or syngamy.<sup>66</sup> ‘The resulting egg/ oocyte is encouraged to initiate development’<sup>67</sup> and the entity goes straight to cleavage/ mitotic division, leading to morula and then blastocyst.<sup>68</sup> The working party acknowledged that a number of these emerging technologies provide entities that do not involve the contribution of DNA from both sperm and egg or the completion of syngamy.

The working party suggested that decision on such matters could be based on the potential for continued development towards a new living being.<sup>69</sup> They went on to argue that the most appropriate marker for defining this potential may be the presence of the primitive streak because at this stage, that the multicellular entity that will form the new individual, first appears.<sup>70</sup>

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<sup>63</sup> President’s Council Report at 153-154

<sup>64</sup> DP at 15

<sup>65</sup> Ibid as argued by Morgan and Ford in Morgan D and Ford M, ‘Cell Phoney: Human Cloning after Quintavalle’ (2004) 30 *Journal of Medical Ethics* 524-526. Professor Margaret Brazier pointed out that SCNT constitutes propagation rather than fertilisation in Brazier M, ‘Regulating the Reproductive Business’ (1999) 7 *Medical Law Review* 166-193 at 189. She drew an analogy to the propagation of a new rose as distinct from a rose arising from fertilisation

<sup>66</sup> Table 1 at DP at 16

<sup>67</sup> Ibid at 21

<sup>68</sup> Ibid at 16, see table 1

<sup>69</sup> DP at 15

<sup>70</sup> DP at 25

Although it has been argued elsewhere that if the entity is placed into correct environment, in theory a viable individual could be produced,<sup>71</sup> the NHMRC working party noted that there is no credible evidence of any cloned human beings having been born.<sup>72</sup> In several mammal species like mice, sheep and cows, SCNT has resulted in live births that developed into healthy adult animals. This suggests that the same could be achieved in humans but the paper also acknowledges that with the current state of the art, it appears that a SCNT blastocyst is likely to have a significantly lower probability of successful development than one created by gamete fertilisation.<sup>73</sup> Nevertheless, the working party concluded that the SCNT blastocyst is a human embryo.

However, to date, there is still no evidence that the blastocyst, if implanted in a womb of a woman, will result in live birth. In addition, SCNT is a process which does not involve the male gamete, sperm, and does not go through fertilisation and syngamy.

After discussion and consideration of all the issues set out above, the NHMRC working party proposed the following definition of the human embryo:

- ‘A human embryo is a discrete entity that has arisen from either:
- a) the first mitotic division when the fertilisation of a human oocyte by a human sperm is complete; or  
any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and
  - b) has not yet reached eight weeks of development since the first mitotic division.’<sup>74</sup>

It is noted that the definition in (b) does not specify whether the conceptus, that is fertilised entity during the first 14 (or 16) days, is an embryo; it only provides ‘... that has the potential to develop up to, or beyond the stage at which primitive streak appears.’ The working party explained that while many historical definitions of embryo have been based on the appearance of the primitive streak in the past 20

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<sup>71</sup> Ibid at 15

<sup>72</sup> Ibid

<sup>73</sup> Ibid at 21. See also Findlay JK et al ‘Human Embryo: A Biological Definition’ (2007) 22 *Human Reproduction* 905-911

<sup>74</sup> Ibid at 27



years, the term has also encompassed the conceptus.<sup>75</sup> Embryologists have been unable to agree on a universally acceptable definition.<sup>76</sup> Given this ongoing dilemma, the working party stated that it would be counterproductive to develop another definition.<sup>77</sup> However, it was acknowledged there is a need to make reference to a development time point, that is, primitive streak.

The early human embryo in the first 14 days is a collection of cells that has not developed into an embryo and the SCNT blastocyst, which does not involve egg and sperm fertilisation and therefore does not go through syngamy, should not be regarded as a human embryo. During the SCNT process, ‘the resulting oocyte is encouraged to initiate development’<sup>78</sup> and the entity goes straight to cleavage/mitotic division, leading to morula and then blastocyst<sup>79</sup> and there is no evidence, only the theoretical possibility, that the human SCNT blastocyst, if implanted into the womb of a woman, can result in a live birth.

However, it is noted that an SCNT embryo is also widely regarded as a human embryo.<sup>80</sup> The present Australian legislation on stem cell research and cloning reflects this view.<sup>81</sup> While the legislation currently permits human embryo research, including SCNT, such research can be undertaken only under strict licence and ethical oversight. Conducting SCNT research without a licence is a specific statutory offence. The statutory constraints take into consideration the concerns raised about embryo research in Australia by imposing a number of stringent controls on the circumstances in which human embryos may be used in research, limiting the number of embryos to those which are necessary to attain significant results and imposing criminal penalty for breach.<sup>82</sup> Other statutory offences include

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<sup>75</sup> DP at 29

<sup>76</sup> Ibid

<sup>77</sup> Ibid at 25

<sup>78</sup> Ibid at 21

<sup>79</sup> Ibid at 16, see Table 1

<sup>80</sup> This is the second of the three views expressed on the moral status of the human embryo discussed in Chapter 1.3 of this thesis. See also President Council’s on Bioethics, *Human Cloning and Human Dignity: The Report of the President’s Council on Bioethics* (President’s Council Report), Public Affairs, New York, 2002 at 152-157 which provides that the SCNT embryo has the potential to develop into an adult being

<sup>81</sup> See Chapter 4.6.2 of this thesis which explores the stringent controls imposed on the research by the *Research Involving Human Embryos Act 2002* (RIHE Act 2002)

<sup>82</sup> The concerns about the ethics of research involving SCNT embryos were raised in a number of submissions received by the Lockhart committee; see Legislation Review Committee

prohibiting human cloning for reproduction and allowing an embryo to develop longer than 14 days. These strict statutory controls are the result of the interpretation that the embryo, whether ART or SCNT embryo, is regarded as a human embryo with a potential to develop into an adult being and if implanted into a womb of a woman, may result in a live birth.

In summary, the early human embryo in the first 14 days is a mere collection of cells that has not developed into an embryo. Also, the SCNT blastocyst does not involve egg and sperm fertilisation and therefore does not go through syngamy and finally, there is only theoretical possibility that the blastocyst can result in a live birth if implanted into the body of a woman. Accordingly, the NHMRC working party's biological definition of a human embryo is critical in informing regulators as they adopt appropriate regulation to control HESC research with conditions.<sup>83</sup>

## **2.7 ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS<sup>84</sup>**

Ethical concerns about HESC research have led scientists to search for other methods to derive stem cells, which do not involve the destruction of embryos. Several recent scientific discoveries constitute alternative methods to HESC research. These sidestep the ethical dilemma associated with HESC research and so are considered as morally acceptable ways to obtain stem cells. Yet each also presents challenges, scientific and ethical.

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Report (Lockhart Report) at 69-75 and by the Heerey committee; see Report of the Independent Review of the *Prohibition of Human Cloning for Reproduction Act 2002* and *Research Involving Human Embryos Act 2002* (Heerey Report) at 44-54

<sup>83</sup> The DP's biological definition of a human embryo was influential in Australia's regulatory framework; see chapters 4-6 of this thesis

<sup>84</sup> This section of the chapter refers substantially to the article by Green R, 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' (2007) 8 *Nature* 480-485

### 2.7.1 ALTERED NUCLEAR TRANSFER (ANT)<sup>85</sup>

This technique, proposed by Professor William Hurlbut, a member of the President's Council on Bioethics in the US, involves the creation of an embryo-like entity with altered DNA where the entity is engineered to lack the capacity to develop into a human baby but will produce usable stem cells. The process is the same as SCNT but the somatic cell nucleus that would be transferred into the egg would first be genetically altered in vitro to impair the resulting embryo's developmental capacity and no embryo is generated.<sup>86</sup> The gene CDx2 that is 'responsible for placental developmental is switched off [and] the resulting entity would lack the capacity of the self-directed integrated organic function that is essential for embryogenesis.'<sup>87</sup> Hurlbut's proposal is based on the observation that a mouse embryo carrying a mutation in the Cdx2 gene dies at the blastocyst stage because it fails to form a trophectoderm from which the placenta normally develops.<sup>88</sup> He argues that a human embryo with a similar mutation would lack the capacity to become a human being and thus represent an ethically uncontroversial source of human embryonic stem cells. He said the resulting entity would have '... no inherent principle of unity, no coherent drive in the direction of the mature human form and no claim on the moral status due to a developing human life.'<sup>89</sup> He has described them as biological artifacts, a human creation for human ends.

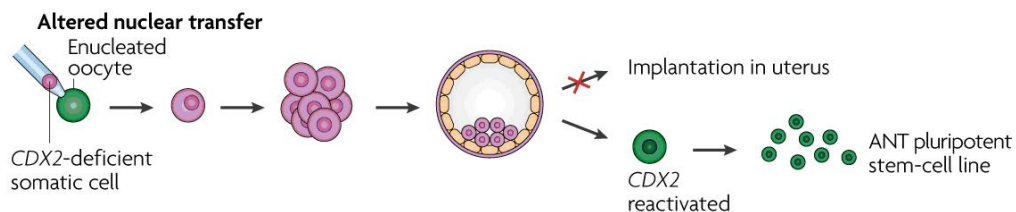


Figure 7: Reprinted with permission from Macmillan Publishers Ltd: Nature, <http://www.nature.com/nrg/journal/v8/n6/pdf/nrg2066.pdf>, 2007

<sup>85</sup> *Understanding Stem cells* at 12, Green R, 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' (2007) 8 *Nature* 480-485 at 480-482 and presentation paper by Hurlbut in 'Altered Nuclear Transfer as a Morally Acceptable Means to Procure Human Pluripotent Stem Cells' <http://alterednucleartransfer.com/> (9 March 2010) and 'Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells' <http://bioethicsprint.bioethics.gov/background/hurlbut.html> (9 March 2010)

<sup>86</sup> See 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' at 480

<sup>87</sup> *Ibid*

<sup>88</sup> Hurlbut W, 'Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells' <http://bioethicsprint.bioethics.gov/background/hurlbut.html> (9 March 2010)

<sup>89</sup> *Ibid*

However, genetic manipulation is difficult. It remains uncertain whether the impairment of Cdx2 compromises the usefulness of the stem cells, and whether it is possible to reactivate the gene when needed.<sup>90</sup>

The idea of deliberately creating defective embryos has met with serious objections from ethicists, especially from those who equate early human embryo with a human being. It attracts the objections critics have voiced about therapeutic cloning. It has even been compared to the deliberate creation of anencephalic infant, lacking a cerebrum, as an organ donor.<sup>91</sup>

Even among stem-cell researchers, concerns have been expressed with this approach.<sup>92</sup> They explain that the embryo develops normally until Cdx2 function is required, at which point they die.<sup>93</sup>

### **2.7.2 PARTHENOGENESIS<sup>94</sup>**

The process of parthenogenesis involves the manipulation of female gametes/ sex cells, that is, eggs. An egg can be developed into an embryo without fertilisation by sperm. A team of scientists from the Harvard Stem Cell Institute has reported the isolation of parthenogenetic embryonic stem cells (PESCs) in mice.<sup>95</sup>

Unlike ANT, this process does not involve the deliberate impairment of an embryo-like entity since the parthenogenotes naturally lack the ability to develop into fetuses. Only gametes, in this case, eggs, are manipulated rather than embryos.

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<sup>90</sup> Green R, 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' at 481

<sup>91</sup> Ibid

<sup>92</sup> Melton D, Daley G & Jennings C, 'Altered Nuclear Transfer in Stem Cell Research- a Flawed Proposal' (2004) 351 *New England Journal of Medicine* 2791-2792. William replied to them in (2005) 352 *New England Journal of Medicine* 1153-1154 to which he did receive a reply from them (same pages)

<sup>93</sup> Melton D, Daley G & Jennings C, 'Altered Nuclear Transfer in Stem Cell Research- a Flawed Proposal' at 2792

<sup>94</sup> Green R, 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' at 482. See also Mai Q et al, 'Derivation of Human Embryonic Stem Cell lines from Parthenogenetic Blastocysts' (2007) *Cell Research* 1008-1019

<sup>95</sup> Kim K et al, 'Histocompatible Embryonic Stem Cells by Parthenogenesis' (2007) 315 *Science* 482-486

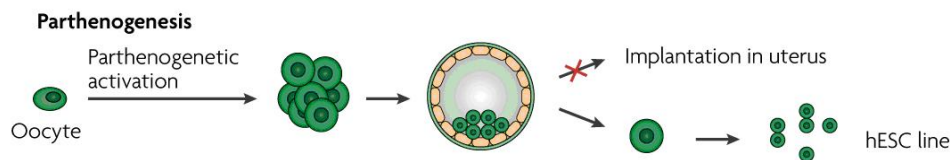


Figure 8: Reprinted with permission from Macmillan Publishers Ltd: Nature, <http://www.nature.com/nrg/journal/v8/n6/pdf/nrg2066.pdf>, 2007

However, there is the question of whether it is possible to extend this technology to human cells and the absence of paternal imprinting may affect the usefulness of the resulting pes lines.<sup>96</sup> These issues are deeply implicated in ethical and religious issues.<sup>97</sup> To some religious people, this is a sensitive issue as it evokes themes from religious traditions in which virgin birth is depicted. In addition, a parthenogenetic embryo has some capacity for development, and there are some who might regard an artificially stimulated egg as equivalent to a human embryo. However, parthogenes are mere sex cells that naturally lack full developmental capacity. The UK Report of the Committee of Inquiry into Human Fertilisation and Embryology (Warnock report) stated:

‘... the ovum and sperm have the potential for becoming a human and yet their loss at menstruation and ejaculation ... is accepted ... neither alone, even in the most favourable environment, will develop into a human person. They do not have this potential ...’<sup>98</sup>

Nevertheless, the value of this technique remains uncertain at the present time.

### 2.7.3 USE OF ORGANISMICALLY DEAD EMBRYOS<sup>99</sup>

This method, that proposes the use of human embryos when they are organismically dead, draws on the principle that it is morally and ethically appropriate to use cadaver organ donation for transplant and research. An embryo is considered dead when it has not experienced cell division between consecutive monitoring not less than 24 hours apart or it has been allowed to succumb at room temperature for not less than 24 hours.<sup>100</sup> It was also proposed that the absence of the transcription factor OCT4, also known as POU5FI, a determinant of growth and differentiation,

<sup>96</sup> Green R, See ‘Can We Develop Ethically Universal Embryonic Stem-cell Lines?’ at 482

<sup>97</sup> Ibid

<sup>98</sup> See 91 of Warnock Report

<sup>99</sup> Green R, See ‘Can We Develop Ethically Universal Embryonic Stem-cell Lines?’ at 482

<sup>100</sup> NHMRC Embryo Research Licensing Committee, *Information Kit* (2008) at 9

marks the death of the embryo.<sup>101</sup> It was further suggested that it is possible to remove healthy stem cells from a dead embryo in the form of organ donation.<sup>102</sup> This is technologically simple and there is a steady supply of dead embryos from in vitro fertilisation.<sup>103</sup> The proposal of using the cells from organismically dead embryos is borrowed from the idea of the determination of brain death of a person where at this point, the removal of vital organs for transplant is ethical as well as legal.<sup>104</sup>

With appropriate consent, it is generally acceptable to use cadaver organ donation for research or transplant. The use of dead embryos is no different, but presents major scientific challenges. To create a stem cell line from a dead embryo, some viable cells must exist.<sup>105</sup> Clinical experience indicates that embryos with grave impairments and a few blastomeres have nonetheless proceeded to normal development. It is not agreed on what the moment of death looks like in an embryo as the absence of vital organs makes it a challenge to establish organismic death. It is questionable whether 'biomarkers of sufficient reliability to certify death is found.'<sup>106</sup> So the serious concern is that this procedure might kill viable embryos.

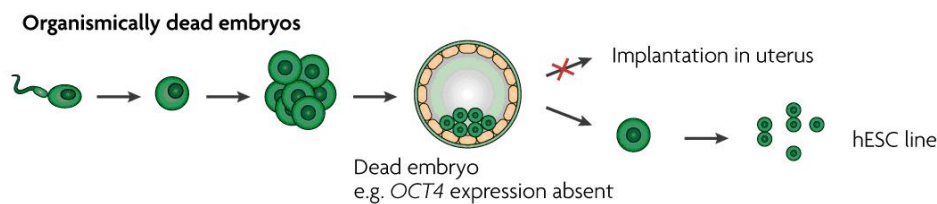


Figure 9: Reprinted with permission from Macmillan Publishers Ltd: Nature, <http://www.nature.com/nrg/journal/v8/n6/pdf/nrg2066.pdf>, 2007

#### 2.7.4 USE OF CHROMOSOMALLY ABNORMAL EMBRYOS<sup>107</sup>

Embryos which are chromosomally abnormal are set aside by IVF clinicians. As they are likely to be genetically compromised, they are not normally considered suitable sources of HESC lines. In addition, these embryos could be used to study

<sup>101</sup> Landry D & Zucker H, 'Embryonic Death and the Creation of Human Embryonic Stem Cells' (2004) *Journal of Clinical Investigation* 1184-1186

<sup>102</sup> Ibid

<sup>103</sup> Ibid at 1186

<sup>104</sup> Ibid at 1185

<sup>105</sup> Green R, See 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' at 482

<sup>106</sup> Ibid

<sup>107</sup> Ibid

faults in embryonic development. However, a 2005 study indicated that chromosomal self-normalisation occurs in a significant proportion of chromosomally abnormal embryos, which raises the possibility of using them for HESC derivation.<sup>108</sup>

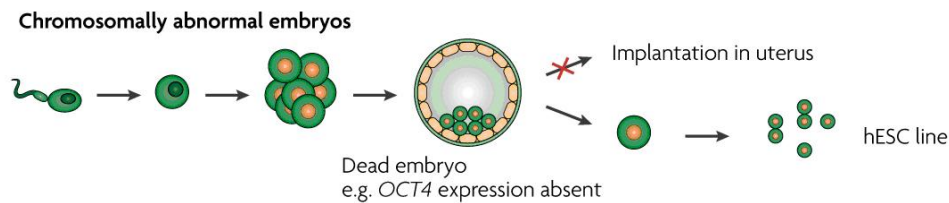


Figure 10: Reprinted with permission from Macmillan Publishers Ltd: Nature, <http://www.nature.com/nrg/journal/v8/n6/pdf/nrg2066.pdf>, 2007

However, it is uncertain whether chromosomally abnormal embryos can provide stable and safe HESC lines for transplant purposes.<sup>109</sup> There are again ethical considerations. There is opposition from those who regard the use of the embryos of genetically diseased or disabled person as unethical, with the potential to lead to the killing of the disabled.<sup>110</sup> Some also argue that because some of these embryos can normalise, the process is tantamount to the destruction of healthy and viable human beings.

### 2.7.5 SINGLE-BLASTOMERE BIOPSY (SBB)<sup>111</sup>

In single-blastomere biopsy, also known as preimplantation genetic diagnosis (PGD), before the IVF embryo is implanted in the mother, a biopsy is performed on the embryo in order to remove a few stem cells from it. Such biopsies are routinely performed by doctors when couples wish to verify that their embryo does not harbour a genetic disease.

At the 8-16 cell stage, a single blastomere is removed by micromanipulation.<sup>112</sup> After being cultured overnight, the cell divides. One cell could be used for genetic diagnosis and the other for the creation of an HESC line. In 2005 a biotechnology company, Advanced Cell Technology (ACT), reported the process of using SBB to

<sup>108</sup> Munne S et al, 'Self Correction of Chromosomally Abnormal Embryos in Culture and Implications for Stem Cell Production' (2005) *Fertilisation Sterilisation* 1328-1334

<sup>109</sup> Green R, See 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' at 482

<sup>110</sup> Ibid

<sup>111</sup> Ibid at 483

<sup>112</sup> Vogel G, 'Scientists Derive Line from Single Embryo Cell' (2006) 313 *Science* 1031

develop pluripotent mouse stem cells lines.<sup>113</sup> In the following year, it reported that it had repeated this experiment with human embryos, this time with thawed ones that were donated for research.<sup>114</sup> With 16 embryos, it obtained two stable HESCs.<sup>115</sup> However, this second paper has been criticised as all 16 embryos have been destroyed.<sup>116</sup> 91 cells were used from 16 embryos, as opposed to just one cell. With the creation of only two stem-cell lines, the efficiency, at 2%, is low.

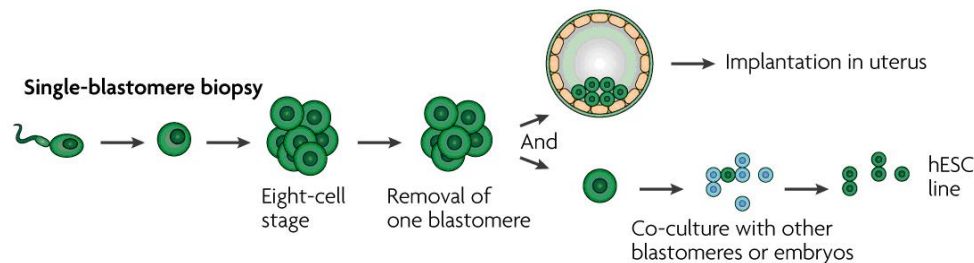


Figure 11: Reprinted with permission from Macmillan Publishers Ltd: Nature, <http://www.nature.com/nrg/journal/v8/n6/pdf/nrg2066.pdf>, 2007

### 2.7.6 INDUCED PLURIPOTENT STEM CELLS<sup>117</sup>

Induced pluripotent stem cells (IPS cells) are adult cells that have been reprogrammed into a pluripotent embryonic-like state. They display key properties of self-renewal and the ability to mature into many different cell types.

This scientific breakthrough was pioneered by two Japanese scientists, Dr Shinya Yamanaka and Kazutoshi Takahashi and published in 2006.<sup>118</sup> They discovered a way to genetically reprogram an ordinary mouse skin cell. Cells were taken from a mouse tail tip and reprogrammed to revert to an embryo-like state, without ever creating the embryo. The researchers used four genes, which were inserted into a

<sup>113</sup> Lanza R et al, 'Embryonic and Extraembryonic Stem Cell Lines Derived from Single Mouse Blastomeres' (2005) 439 *Nature* 216-219. ACT is an American private biotechnology company which focuses on stem cell research. Robert Lanza is the director of the company

<sup>114</sup> Lanza R et al, 'Human Embryonic Stem Cell lines Derived from Single Blastomeres' (2006) *Nature* <http://www.nature.com/nature/journal/v444/n7118/full/nature05142.html> (12 June 2010)

<sup>115</sup> Abbott A, 'Ethical Stem-Cell Paper under Attack' (2006) 443 *Nature* 12

<sup>116</sup> Ibid

<sup>117</sup> National Institute of Health (NIH) refers to it as IPSCs. This is also known as somatic cell dedifferentiation in the article 'Can we develop ethically universal embryonic stem-cell lines?' at 484

<sup>118</sup> Takahashi K & Yamanaka S, 'Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors' (2006) *Cell* 663-676. They are based in Kyoto University, Japan. This announcement was made on June 2006



fibroblast, cultured skin cells. Virus vectors were used to carry extra genes which would modify the skin cells.

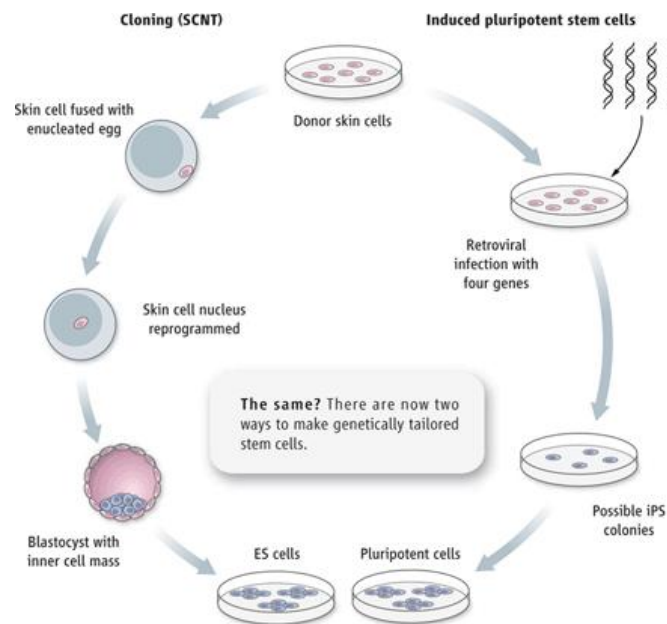


Figure 12: IPS process compared to SCNT process. From Holden C & Vogel G , 'A Seismic shift for Stem Cell Research' 319 *Science* 1 Feb 2008 at 561. Reprinted with permission from AAAS

Other scientists sought to repeat the experiment in humans. Sixteen months later (November 2007), Yamanaka's group<sup>119</sup> and James Thomson's group<sup>120</sup> simultaneously reported the generation of IPS cells from human fibroblasts. Thomson's reprogramming involved the use of a mix of slightly different set of genes from Yamanaka's cocktail.

There have been incremental advances toward greater efficiency and speed in this field. The IPS cells method was improved by a team from the Salk Institute for Biological Research using human hair. Cells were taken from the root of a hair follicle called keratinocytes. As a matter of comparison, the Japanese team needed 10,000 tissue cells to create one IPS cell whereas the Salk team used about only 100 cells to create one IPS cell. The Japanese team took about a month to reprogram the

<sup>119</sup> Takahashi K et al, 'Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors' (2007) 131 *Cell* 861-872

<sup>120</sup> Yu J et al, 'Induced Pluripotent Stem Cell lines Derived from Human Somatic Cells' (2007) 318 *Science* 1917-1920

cells whereas the Salk team achieved in a week.<sup>121</sup> This required generating 100 times more cells in half the time. In addition, researchers have been attempting to discover whether only certain cell types can be reprogrammed and in a recent study, liver and stomach cells have been converted to pluripotency.<sup>122</sup>

There are three potential applications for IPS cells.<sup>123</sup> First, IPS cells, which are relatively easily generated, are already available to study cells' differentiation and comparison between healthy and diseased cells. Secondly, in the near future these cells will be available for drug screening and testings, which previously have been carried out only in animals. Compared to SCNT, IPS cells may be not only easier to use but possibly better as the cells 'share both nuclear and mitochondrial DNA with the original patient, whereas cells derived by SCNT carry only the same nuclear DNA.' The third application, in the more distant future, is in regenerative medicine. A group has already 'successfully treated transgenic mice carrying the human gene for sickle-cell anaemia by giving them haematopoietic stem cells derived from those mice's gene-repaired IPS'. Opponents of HESC research argue that IPS cells present the best alternative as the cells appear to have the same therapeutic potential without destroying embryos in the process, and the risk of rejection would be eliminated as IPS cells are created from skin cells taken from the recipient.

It has been argued that IPS cells, along with the other stem cell alternatives, could end the debate on HESC research. Some scientists, including prominent ones like Sir Ian Wilmut<sup>124</sup> and Professor James Thomson,<sup>125</sup> have announced shifting their emphasis to IPS. In addition, other groups in prominent universities are working aggressively on IPS. For example, Kevin Eggan's group at Harvard is collecting skin cell from patients with amyotrophic lateral sclerosis to generate IPS cell lines.

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- <sup>121</sup> Baker M, 'Embryonic-like Stem Cells from a Single Human Hair' (2008) *Nature Reports*, [http://www.cmrb.eu/media/upload/pdf/NatureArticle\\_editora\\_251\\_124.pdf](http://www.cmrb.eu/media/upload/pdf/NatureArticle_editora_251_124.pdf) (18 June 2010)
- <sup>122</sup> Aoi T et al, 'Generation of Pluripotent Stem Cells from Adult Mouse Liver and Stomach cells' (2008) 321 *Science* 699-702
- <sup>123</sup> Goldman B, 'Embryonic Stem Cells 2.0' (2008) <http://www.nature.com/stemcells/2008/0805/080501/full/stemcells.2008.67.html> (11 June 2010)
- <sup>124</sup> Blackman S, 'Promises, Promises, Ill Judged Predictions can be Embarrassing at Best and at Worst, Damaging to the Authority of Science and Science policy' (2009) <http://www.the-scientist.com/article/display/56082/> (11 June 2010)
- <sup>125</sup> Baker M, 'James Thomson: Shifts from Embryonic Stem Cells to Induced Pluripotency' (2008) <http://www.nature.com/stemcells/2008/0808/080814/full/stemcells.2008.118.html?> (11 June 2010)

Lawrence Goldstein's group at University of California, San Diego, collect skin biopsies for Alzheimer's patients.<sup>126</sup>

While it is important that IPS cells could be used for regenerative medicine in humans, there remain major issues to be resolved. First, when IPS cells are introduced into the body, there is the serious risk of triggering cancer cells. Two of the four genes used in the original cocktail to create IPS cells are oncogenes that have the potential to turn the IPS cells cancerous. c-Myc is a known oncogene whose over expression can cause cancer.<sup>127</sup> This means that IPS cells are currently unsafe for human use and therefore their therapeutic value is limited. Researchers at the Whitehead Institute for Medical Research<sup>128</sup> substituted the c-Myc with a drug-like molecule called Wnt3a.<sup>129</sup> This molecule promotes the conversion of adult cells into IPC cells. While the technique is promising in mouse cells, its potential application in humans has not been studied. In addition, the viruses currently employed in the process, called retroviruses, are associated with cancer because they insert DNA anywhere in the cell's genome. In animal studies, the virus used to introduce the stem cell factors sometimes causes cancer. There are studies being conducted to overcome this obstacle.

- A team of Harvard researchers led by Konrad Hochedlinger used adenovirus, the common cold virus, instead of retrovirus vectors to carry the genes into mature cells of the mice and force them to act like ESCs. However, the studies are inconclusive and more research is required. The main concern is that processes that work in mice do not always work in humans.<sup>130</sup>
- Two teams in the UK and Canada used a technique called 'electroporation' to insert the genes through pores rather than using viruses. The genes were

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<sup>126</sup> Holden C & Vogel G, 'A Seismic Shift for Stem Cell Research' (2008) 319 *Science* 560-563 at 560

<sup>127</sup> Jaenisch R et al, 'Wnt Signaling Promotes Reprogramming of Somatic cells to Pluripotency' (2008) 3 *Cell Stem Cell* 132-135

<sup>128</sup> This is a nonprofit independent research and educational institution in Cambridge, Massachusetts, USA

<sup>129</sup> See Jaenisch R et al, 'Wnt Signaling Promotes Reprogramming of Somatic cells to Pluripotency' at 132. This research was supported by the National Institute of Health

<sup>130</sup> Hajek H, 'Stem cell Breakthrough' (2008) <http://www.healthnews.com/medical-updates/stem-cell-breakthrough-1849.html> (10 June 2010)

later removed making the cells entirely free of foreign DNA.<sup>131</sup> However, the efficiency of the process is said to need improvement.<sup>132</sup>

- A California biotech company claims to have used carbon nanotubes to reprogram adult human cells which removed the risk of cancer. However, this has not been reported in a peer-reviewed journal.<sup>133</sup>

In addition, there are other disadvantages and serious concerns about IPS cells, which include the following:

- ‘Random insertion of retrovirus into the genome carries the risk of accidental turning on or off some key gene inappropriately, possibly later in development’,<sup>134</sup>
- IPS cells created in a laboratory dish may not find their way to a diseased organ located deep inside the human body;<sup>135</sup>
- As the genome clock is not completely reset, this is likely to play a role in the development of health problems seen in cloned animals. This raises the serious concern that tissue developed from reprogrammed IPS cells might not function normally. For instance, Dolly developed lung disease and as a result was euthanised;<sup>136</sup>
- The extent to which a person’s genome can be reset varies from individual to individual. This means that each person requires individualised reprogramming regimen in order to create IPS cells for therapeutic use. An agency like the US Food and Drug Administration is unlikely to approve such an individualised protocol, as it endorses strict uniformity and conformity on therapeutic protocols but not different protocols for different persons;<sup>137</sup> and

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<sup>131</sup> The two teams are the University of Toronto and the Medical Research Council Centre of Regenerative Medicine at the University of Edinburgh, *Bionews* 23 February 2009

<sup>132</sup> This is according to Dr Keisuke Kaji, who led the study at the University of Edinburgh, *Bionews* 23 February 2009

<sup>133</sup> Cyranoski D & Baker M, ‘Stem-cell Claim Gets Cold Reception’ (2008) 452 *Nature* 132

<sup>134</sup> See Goldman B, ‘Embryonic Stem Cells 2.0’

<sup>135</sup> Scadden D & Komaroff A, ‘Will Stem Cells Finally Deliver?’ (2008) <http://www.newsweek.com/2008/12/05/will-stem-cells-finally-deliver.html> (6 July 2010). The authors are professors in Harvard Medical School

<sup>136</sup> This is the opinion of Eric Forsberg, Director of the WiCell Research Institute in Clark S, ‘Induced Pluripotent Stem Cells Steal Limelight from Embryonic Stem Cells’ (2009) <http://wistechnology.com/articles/5331/> (6 July 2010)

<sup>137</sup> Clark S, ‘Induced Pluripotent Stem Cells Steal Limelight from Embryonic Stem Cells’ (2009) <http://wistechnology.com/articles/5331/> (6 July 2010)

- The process is inefficient. The four genes managed to reprogram just one out of 1,000 cells that received them.<sup>138</sup> At only less than one percent, the efficiency of this process is low.<sup>139</sup>

Two studies, reported in 2010, comparing IPS cells with HESC suggest that are significant advantages with using HESC for research purposes. In one study, Robert Lanza and Shi Jiang Ku compared the two in the differentiation into several kinds of blood and discovered that HESC lines made more than 1000 times cells than IPS cell lines and in addition, some IPS cells ‘undergo cellular aging and programmed death after a short time in culture’.<sup>140</sup> In another study, Professors James Thomson and Su Chun Zhang also compared HESC with IPS cells in the differentiation into neuronal cells and discovered that 90% of HESC responded to the chemical recipe for making neural cells but with IPS cells, they are more variable; in some lines only 15% turned into neuronal cells, in another, 79%.<sup>141</sup> Lanza’s view on IPS cells is that ‘these cells are pretty screwed up’.<sup>142</sup>

Even if IPS cells eventually prove safe for use in humans, scientists claim that generating individually tailored cell populations for every patient is an unrealistic expectation. Patient specific therapy is impractical as millions of lines are needed.<sup>143</sup> Moreover, there is insufficient time to generate the cells if they are needed urgently after a heart attack or a spinal injury as it takes about six months to make a cell line.<sup>144</sup>

It remains uncertain whether IPS cells are the absolute equivalent of HESCs.<sup>145</sup> In addition, there is a need to study the development of early human embryos, through which scientists hope to answer questions about the origins of chromosomal abnormalities and the diseases they cause. These questions cannot be answered by

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<sup>138</sup> Vogel G, ‘Four Genes Confer Embryonic Potential’ (2006) 313 *Science* 27

<sup>139</sup> Costello J, ‘Tips of Priming Potency’ (2008) 454 *Nature* 45-46 at 45

<sup>140</sup> Vogel G, ‘Reprogrammed Cells Come up Short, for now’ (2010) 327 *Science* 1191

<sup>141</sup> *Ibid* at 45

<sup>142</sup> *Ibid*

<sup>143</sup> This is the view of Robert Lanza of ACT, Holden C and Vogel G, ‘A Seismic Shift for Stem Cell Research’ (2008) 319 *Science* 560-563 at 563

<sup>144</sup> This is the view of Professor Stephen Minger of King’s College London, *ibid*

<sup>145</sup> This is the view of George Daley, Harvard stem cell researcher, see Holden C and Vogel G, ‘A Seismic Shift for Stem Cell Research’ at 561

studying some manipulation of an adult skin cell. On the other hand, SCNT generates an embryo, so it can address questions about early development that direct reprogramming cannot.<sup>146</sup>

HESCs are still considered as epitome for stem cell research.<sup>147</sup> An adult skin cell, which is decades old, will inevitably have been altered by aging or toxins compared to a pure crystal human embryo.<sup>148</sup>

With all the various issues about IPS cells, Thomson has described them as ‘dark clouds on the horizon.’<sup>149</sup> In addition, it is speculated that it will take a long time before IPS cells are likely to find clinical use; ESCs will likely to find clinical use before IPS cells do. It is premature at this stage to abandon HESC research.<sup>150</sup>

While there are a number of shortcomings and uncertainties about IPS cells, it is argued that the risks associated with this new technology should not be a reason not to pursue the research at all. Scientists should not pursue research only if they are confident that it would lead to successful outcomes.<sup>151</sup> It is therefore argued that all types of stem cell research, adult stem cell, HESC and IPS cells, need to be pursued

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<sup>146</sup> This is the opinion of George Daley, *ibid* at 563

<sup>147</sup> This is the opinion of some scientists and doctors including Dr Robert Jansen, Medical Director of Sydney IVF Ltd in a face-to-face interview on 30 October 2009, interview by Chee Kuen Foong (Patrick) and Harvard Stem Cell Institute; see Hochedlinger K, ‘Your Inner Healers’ (2010) *Scientific American* 29-35 at 35. HESC research continues apace in USA as money is flowing in California from the Californian Institute for Regenerative Medicine (CIRM). Two groups at Harvard remain intent on generating cell lines for cloned embryos. For Renee Reijo Pera of Stanford University, SCNT remains the only tool of her purpose which is to learn how to bypass defects in egg reprogramming in order to help infertile women

<sup>148</sup> This is the opinion of Thomas Okarma, the president of the company, Geron Corp, see Holden C & Vogel G, ‘A Seismic Shift for Stem Cell Research’ at 561

<sup>149</sup> Clark S, ‘Induced Pluripotent Stem Cells Steal Limelight from Embryonic Stem Cells’ (2009) *Wisconsin Technology News*

<sup>150</sup> This is the opinion of Douglas Melton, a Harvard stem cell biologist, see Holden C & Vogel G, ‘A Seismic Shift for Stem Cell Research’ at 563

<sup>151</sup> There has been some recent success with the use of IPS cells. The IPS cell technology have been used to generate several disease specific cell lines for diseases like diabetes, Parkinson’s Disease, spinal muscular atrophy, Huntington’s Disease and Down’s Syndrome. One of the more recent success is the team from Monash University and CSIRO that reported they generated IPS cells from human kidney cells. The results suggest that reprogrammed kidney induced pluripotent stem cells may assist the study of genetic kidney diseases which could lead to novel therapies, see Song B et al, ‘Generation of Induced Pluripotent Stem Cells from Human Kidney Mesangial Cells (2011) *Journal of the American Society of Nephrology* <http://jasn.asnjournals.org/content/early/2011/05/12/ASN.2010101022.abstract> (6 December 2011)

simultaneously and the hope is that over time, scientists continue to improve and attempt to perfect theirs and other scientists' techniques.

## **2.8 THE CREATION OF CYTOPLASMIC HYBRIDS/ CYBRIDS**

The creation of cytoplasmic hybrids, otherwise known as cybrids, may prove important for SCNT research but is controversial and illegal in Australia. One of the arguments raised against HESC research is the serious concern expressed over the limited supply of human eggs, a vital ingredient for the research.<sup>152</sup> The chapter argues that animal eggs could be used as a substitute for human eggs.

There are four types of hybrid embryos and the type relevant for the argument of this thesis is known as cytoplasmic hybrid or cybrid.<sup>153</sup> A cybrid is created by transferring the nuclei of human cells, such as skin cells, into an animal egg from which almost all of the genetic material have been removed. This innovative approach involves the fusion of the human DNA and an animal egg, instead of human egg, in the production of embryos. The process is similar to that used for the cloning of Dolly. Effectively, the animal egg acts as a shell to carry human DNA. The egg develops into an embryo from which stem cells can be harvested. The cells created in this way can be used for research. The safeguards are that they will never be implanted in a woman and they have to be destroyed at 14 days.<sup>154</sup>

The freshly derived ESCs contain mitochondria from the animal egg as well as the human somatic cell, both of which carry mitochondria DNA. But as the cells grow in culture, the human mitochondria becomes more prevalent and the animal DNA seems to disappear.<sup>155</sup> It has been estimated that a cybrid embryos is 99.9 % human

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<sup>152</sup> In Chapter 4.9.3 of this thesis, the issue of scarcity of human eggs is further explored. The main reason why there are few egg donors is health risks associated with the process of egg extraction. As for eggs from IVF clinic, they are mostly from older women, thus they are not considered as the best eggs

<sup>153</sup> The other three types of hybrids are as follows: First, true hybrid embryo which is the result of fertilising a human egg with animal sperm or vice versa. The second type is chimeric embryo which is made by injecting animal cells into a human embryo, for instance, creating a mouse with 10% human brain cells. The third type is human transgenic embryos, made by injecting animal DNA into a human embryo

<sup>154</sup> These safeguards are necessary to ensure ethical research. See discussion in Chapter 4.9.3 of this thesis

<sup>155</sup> Vogel G, 'Team Claims Success with Cow-Mouse Nuclear Transfer' (2006) 313 *Science* 155-156 at 156

and 0.1% animal<sup>156</sup> and the animal DNA disappears over time.<sup>157</sup>

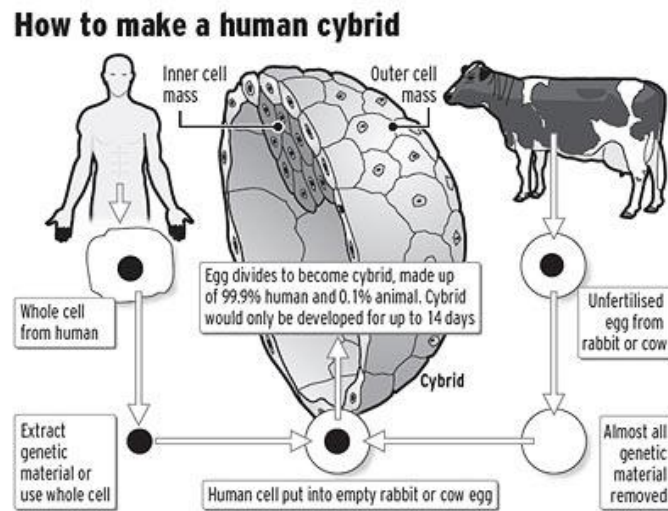


Figure 13: The process of creating cybrids (reprinted with permission from Telegraph Syndication Department, <http://www.telegraph.co.uk/news/uknews/1551781/Scientists-allowed-to-create-hybrid-embryos.html>, Nic Fleming/Telegraph Media Group/2007)

In 2003, Chinese scientists were the first to report that they successfully created human-animal embryos, which in turn yielded human stem cells.<sup>158</sup> The team in Shanghai Second Medical University fused human skin cells with rabbit eggs. They used the foreskins of two five year old boys and two older men, aged 42 and 52, as well as facial tissues from a woman, aged 60. The results suggested that human somatic nuclei can form nuclear transfer somatic embryonic stem cells (NTESCs) independent of the age of the donor. It is interesting that overall there was no significant difference in the percentage of blastocysts that developed in the four age groups. This research demonstrates that the potential of the human somatic cell nucleus to be reprogrammed may not be diminished by ageing. In 2006, a team from South Korea reported that they had success with cow-mouse nuclear transfer.<sup>159</sup>

<sup>156</sup> Chan LP, 'The First Creation of Human-Animal Hybrid Embryo' (2008) <http://sciencelay.com/biology/human-biology/the-first-creation-of-human-animal-hybrid-embryo/> (11 June 2010)

<sup>157</sup> See Vogel G, 'Team Claims Success with Cow-Mouse Nuclear Transfer' at 156

<sup>158</sup> Chen Y et al, 'Embryonic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes' (2003) *Cell Research* 251-263. This is a well known journal in China. However, it is not peer reviewed by the western counterparts

<sup>159</sup> See Vogel G, 'Team Claims Success with Cow-Mouse Nuclear Transfer' at 155. The team from Seoul National University was headed by Chang-Kyu Lee



The eggs from cows and rabbits<sup>160</sup> are plentiful and they are relatively easy to obtain. These animal eggs are provided by abattoirs/ slaughter house from animals which are used for food. A team of UK scientists from Newcastle University claims that they could get 200 cow eggs a day from the local meat industry.<sup>161</sup> They also claim that the process of the creation of cybrids is easier than initially thought and it is relatively easier to collect stem cells from these cybrids.<sup>162</sup> The team has produced 270 cybrids.

However, the creation of cybrids is controversial. There are various objections put forward: the human dignity argument and the concern for animal welfare.<sup>163</sup> For some people, reproduction with animals has been taboo and remains so. Opponents of the process claim that mixing even a small amount of human genetic material with that of an animal is unnatural, objectionable and wrong. Such research has triggered protests from social conservatives. There is also fear expressed of the blurring of species lines, invoking the image of the chimera of Greek mythology: a monstrous mix of lion, goat and serpent. Even among scientists there is scepticism. Professor Sir John Gurdon is of the view that there might be genetic abnormality in cybrids that would not lead to good quality stem cells.<sup>164</sup> Obtaining ESCs for research from a cybrid may not yield useful information for human health care because those cells will always be tainted by the mitochondrial DNA from the animal eggs.

In the UK the *Human Fertilisation and Embryology Act 2008* allows the creation of three types of hybrid embryos including cybrids.<sup>165</sup> Two teams of scientists have already been granted licences by the Human Fertilisation & Embryology Agency (HFEA) to use animal eggs in human embryo stem cell research.<sup>166</sup> The team at King's College London was granted licence to use human-bovine embryos to study

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<sup>160</sup> The fertility of rabbits is legendary

<sup>161</sup> Maden C, 'Human/Animal Hybrid Embryos are 'Easy' to Make' (2008) *Bionews* 23 June 2008. Dr Lyle Armstrong, the leader of Newcastle University research team, made this claim at BIO 2008, a biotechnology conference in San Diego

<sup>162</sup> Ibid

<sup>163</sup> Batty D, 'Q & A: Hybrid Embryos' (2008) <http://www.guardian.co.uk/science/2007/may/17/genetics.health1/print> (7 August 2008)

<sup>164</sup> Professor Gurdon is a Cambridge University researcher, see Batty D, 'Q & A: Hybrid Embryos'

<sup>165</sup> The type of hybrid embryos which is not legalised is true hybrids

<sup>166</sup> See Batty D, 'Q & A: Hybrid Embryos'

degenerative neurological diseases such as Parkinson's and Alzheimer's and the team at Newcastle University's stem cell institute has the licence to use cow eggs to develop stem cells for the treatment of diabetes and spinal paralysis.<sup>167</sup>

However, in Australia the creation of cybrids is prohibited.<sup>168</sup> The debate concerning the legalisation of cybrids is important to the future of SCNT research in the country. These issues will be reconsidered in the review of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Amendment Act 2006)*, to be held in late 2010.<sup>169</sup> It is recommended that Australia should follow UK's lead in this area and legalise the creation of cybrids as an important measure to overcome the problem of short supply of human eggs for SCNT research.

## 2.9 STEM CELL CLINICAL APPLICATION AND THERAPY

Most types of stem cell research have yet to translate to stem cell therapy. At present only a few diseases are likely to be treatable with stem cell therapies because scientists can only regenerate a few types of tissues. There are 2,452 stem cell trials listed in the US National Institutes of Health (NIH). While some have been completed, many are active and still recruiting.<sup>170</sup> Before being introduced as accepted medical procedures, these NIH listed experimental trials are subjected to proper scrutiny and assessment.

In addition, research is still a long way from being able to create whole complex human organs as 'the internal complexity of the structure and function of major human organs, ... with their blood and lymphatic systems and complex tissue

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<sup>167</sup> See *ibid.* However, it is noted that the research has ceased due to lack of research funding from the UK's Medical Research Council, see Mayer S, 'Lack of funding prevents human-animal stem cell research in UK' (2009) *British Medical Journal* 338. Dr Minger was of the opinion that the reviewers considered his grant application was not competitive in the light of lack of overall funding for medical research in UK as well as in comparison to the costs of funding other types of stem cell research such as IPS cells

<sup>168</sup> This is primarily due to the so-called yuck factor; see Chapter 5.5.3 of this thesis. Many countries have prohibited this practice including Canada, France, Germany and Italy

<sup>169</sup> It is a legislatively mandated review as required under section 25A (Sch1)/Section 47A (Sch 2) of the *Amendment Act 2006*. This law review will be conducted at the end of 2010

<sup>170</sup> The United States National Institute of Health Clinical Trials website at <http://www.clinicaltrials.gov/ct2/results?term=stem+cell+trials> (14 April 2009)

structures, make the growth of organs or parts of organs ... a very long term prospect.<sup>171</sup> However, the success of the most established stem cell based therapies such as blood<sup>172</sup> and skin transplants<sup>173</sup> provide hope that in future scientists will be able to develop therapies for diseases previously thought to be incurable. Many major diseases are caused by the loss of a single type of cell or tissue.<sup>174</sup> Finding a cure would be easier if scientists could regrow the missing or damaged cells and implant them into patients.

Many of these trials listed on the NIH register are not using HESCs but autologous cells implanted in the patient who provided the source cells. These are cells taken from an individual, cultured (or stored) and genetically manipulated before being transferred back into the original donor. A number of the trials, particularly in cancer, rely on combinatorial therapy approach, i.e. stem cell therapy combined with other types of therapy to eliminate and control the causes of diseases.<sup>175</sup> For instance, one of the NIH listed clinical trials is ‘Thiotepa-Clofarabine-Busulfan with stem cell transplant for high risk malignancies’.<sup>176</sup>

Clearly, vast amount of stem cell research remains to be undertaken and experimental work must continue. The results are much slower in coming than originally expected. Fundamental research still needs to be done on comparisons between embryonic stem cells, adult stem cells and IPS.

## 2.10 CONCLUSION

The science of stem cell technology has developed considerably since the previous century where cell theory was first developed. New scientific discoveries in stem cell research have significant implications for its future in the application of the elimination and control of diseases and the reparation of existing conditions.

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<sup>171</sup> See *Stem Cell Research: Medical Progress with Responsibility* at 18

<sup>172</sup> Hematopoietic stem cells are found in the blood and bone marrow

<sup>173</sup> For instance, skin grafts; the regenerative capabilities of human skin to treat victims of severe burns as stem cells are located just under the top layer of skin

<sup>174</sup> Type 1 diabetes (juvenile-onset) is caused by the loss of the insulin-producing cells of the pancreas. Similarly, in Parkinson’s disease, this is caused by the loss of a single type of nerve cell

<sup>175</sup> Lu P et al, ‘Combinatorial Therapy with Neurotrophins and CAMP Promotes Axonal Regeneration Beyond Sites of Spinal Cord Injury’ (2004) *Journal of Neuroscience* 6402 - 6409

<sup>176</sup> See <http://www.clinicaltrials.gov/ct2/results?term=stem+cell+trials> (14 April 2009)

Funding is an important issue and it depends very much on the government's support in the research.

The various stem cell alternatives, which at first sight appears to circumvent the need for HESC research, each one presents challenges, both scientific and ethical. It is important to continue to pursue all avenues of research, adult stem cells, HESC and IPS, as the techniques for each will improve and be perfected over time.

It could take some time, possibly years, before stem cell research translates to stem cell therapy. Scientists have warned 'this is only just the beginning'.<sup>177</sup> The thesis warns of the danger in exaggerating the promise of new medical developments as it could lead to a false sense of hope. What could be overpromised is not only the potential outcome of stem cell research but also the time scales that are involved. The basic research needed to develop viable therapeutic options is a lengthy process that may extend over many years and even decades. Even after science has moved from basic research to developing medical applications, it still takes many years to thoroughly test those applications and demonstrate that they are safe to prescribe for patients. This is true for all medical treatments including the development of new drugs, procedures and medical equipment and is not specific to the living cell therapies made possible by stem cell research.

In USA, the Obama administration has lifted the Bush restriction in using federal funding for stem cell research. This has raised some hope not just in America but elsewhere. Obama's move has been described as 'a shot in the arm for ESC science around the world'.<sup>178</sup> It is foreseeable that dynamic research will resume in the USA and this would impact HESC research in other parts of the world. While there

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<sup>177</sup> See *Stem Cell Research: Medical Progress with Responsibility* at 6-7

<sup>178</sup> These were the words of Andrew Laslett, a scientist of the Australian Stem Cell Centre (ASCC) which were agreed by the interim chairman of ASCC, Graham Macdonald in Dayton L, 'Researchers Back in Business' *The Weekend Australian* (March 14-15, 2009) at 14. However, recently the US District judge granted an injunction banning federal funding for HESC research. The US government will appeal against the decision. See Cook M, 'Federal Embryonic Stem Cell Research Funding stopped by Black-Letter Judge' (28 August 2010) *Bioedge* <<http://www.bioedge.org/>> (30 August 2010)

appears to be a levelling-off of the initial excitement about stem cell technology,<sup>179</sup> the excitement has now resurfaced.

These events, especially in the past two years, illustrate that scientific discoveries are unpredictable. Transforming stem cell science into stem cell medicine is the kind of enterprise that requires creativity and patience and partnerships between government, universities and industry within the country and all over the world.<sup>180</sup>

Pursuing HESC research alongside adult stem cells and IPS cells is very important. HESC research, due to its contentious nature, needs to be regulated. As science and the clinical applications progress rapidly, law and policies of nations need to keep pace, presenting a challenge for lawmakers. This raises a fundamental overall question about the legitimate and proper role of regulation in an area that is fast moving and for that reason, in the following chapter, important regulatory theories are examined that will influence the design of an effective regulatory framework to govern such controversial research in Malaysia.

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<sup>179</sup> Chalmers D, 'Stem Cell Technology: From Research Regulation to Clinical Applications' in Campbell A (ed), *Bioethics and the Global Politics of Stem Cell Science: Medical Application in a Pluralistic World*, World Scientific, 2010 (forthcoming)

<sup>180</sup> It is important to build on the networks and collaborations already in place such as with the two famous Australian scientists, Martin Pera and Alan Trounson, who are now based in USA

## 3: THE THEORY OF REGULATION

### 3.1 INTRODUCTION

The fundamental issue raised is whether a nation should regulate human embryonic stem cell (HESC) research or not. If the answer is in the affirmative, the next enquiry is what model of regulation the regulators should consider adopting. It is noted that there are countries that have not adopted any regulation while there are others that have formulated mere guidelines and some nations have passed legislation to strictly regulate HESC research.

This chapter explores the theory of regulation in the context of HESC research, a central theme of this thesis. As this thesis recommends that the Malaysian government should create an effective regulatory framework to regulate HESC research, it is critically important that a defensible theory of regulation, applicable in Malaysia, supports and underpins this recommendation.

The chapter explores the principal challenges that regulators may face in regulating new technologies including stem cell technology and possible options of addressing them. This chapter draws on the work of Professor Roger Brownsword, a prominent expert in issues of technology, ethics and law, who has written extensively on these challenges.<sup>1</sup> A face-to-face interview was conducted with Brownsword to seek his insight of these difficult issues as well as options in attempting to resolve them.<sup>2</sup> In attempting to address the challenges, the chapter evaluates various measures that could be adopted.

The theory of responsive regulation, or what is termed as ‘smart regulation’, is examined in this chapter. Professor John Braithwaite<sup>3</sup> has conducted several

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<sup>1</sup> Professor Roger Brownsword has long been associated with the UK’s House of Commons Science and Technology Committee. This committee’s role is to ensure that the UK Government policy and decision-making are based on good scientific and engineering advice and evidence

<sup>2</sup> The interview was held on 18 November 2009 in his office in the Law faculty, Kings College London

<sup>3</sup> Professor John Braithwaite is a renowned social scientist in Australia National University (ANU). He has won a number of international awards for his research on restorative justice and responsive regulation.

empirical research studies in this area, including the regulation of nursing homes and business. This thesis attempts to apply his theory in the design of the proposed regulatory model that the Malaysian government could adopt in regulating HESC research and a face-to-face interview was conducted with Braithwaite to seek his views.<sup>4</sup> This chapter also explores the concept of tripartism,<sup>5</sup> an aspect of responsive regulatory theory, as a possible solution to the problem of regulatory capture/ corruption.

### 3.2 REGULATORY CHALLENGES<sup>6</sup>

Before establishing any regulatory framework for HESC research, regulators ought to recognise a number of regulatory challenges likely to be encountered. This chapter explores the principal challenges and attempts to address each.

The four main challenges Brownsword identifies are the following: the challenge of achieving ‘regulatory legitimacy’, the challenge of attaining ‘regulatory effectiveness’, the challenge of maintaining ‘regulatory connection’ and the challenge of ‘regulatory cosmopolitanism’.<sup>7</sup> While his writings refer to challenges encountered by regulators generally in regulating new technologies, all of these difficulties are also relevant in the context of the regulation of HESC research.<sup>8</sup> He warns that unless these challenges are successfully addressed, the regulatory environment is defective, ‘as opposed to a regulatory environment that supports the development, application and exploitation of technologies that will contribute to such an overarching purpose, an environment properly geared for risk management and benefit sharing.’<sup>9</sup>

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<sup>4</sup> The interview was held on 19 October 2009 in his office in Australian National University (ANU)

<sup>5</sup> This is discussed in 3.3.2 of this chapter

<sup>6</sup> The discussions on all four challenges are heavily reliant on Brownsword’s publications and additional data and opinion collected in an interview with him

<sup>7</sup> Brownsword R, *Rights, Regulation and Technological Revolution*, Oxford University Press, New York, 2008

<sup>8</sup> The new technologies that Brownsword outlines include the regulation of cybertechnology, nanotechnology, renewable energy technology and biotechnology

<sup>9</sup> Brownsword R & Somsen H, ‘Law, Innovation and Technology: Before We Fast Forward - A Forum for Debate’ (2009) 1 *Law, Innovation and Technology* 1-73 at 3

### 3.2.1 THE FIRST CHALLENGE: ATTAINING REGULATORY LEGITIMACY

For regulators to attain regulatory legitimacy, the regulatory position that they adopt must be considered by all ‘ethical constituencies’<sup>10</sup> in a society as acceptably legitimate and ethically appropriate. However, articulating such a regulatory position is a challenge in a diverse society with a plurality of values. Attempts to regulate biotechnology are particularly susceptible to this difficulty.

In the UK, a report of the Science and Technology Committee, *Human Reproductive Technologies and the Law*, makes the following points:

We accept that a society that is both multi-faith and largely secular, there is never going to be consensus on the level of protection accorded to the embryo or the role of the state in reproductive decision-making. There are no demonstrably “right” answers to the complex ethical, moral and political equations involved. We respect the views of all sides on these issues. We recognise the difficulty of achieving consensus between protagonists in opposing camps in this debate. We believe, however, that to be effective this Committee’s conclusions should seek consensus, as far as it is possible to achieve ....<sup>11</sup>

A type of pluralism, especially relevant in secular societies, is what Brownsword refers to as a ‘bioethical triangle’.<sup>12</sup> It comprises three key ethical constituencies: utilitarian constituency, human rights constituency and human dignity constituency. This kind of pluralism is envisaged in the *Universal Declaration on Bioethics and Human Rights 2005* where Article 4 on ‘Benefit and Harm’ provides:

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximised and any possible harm to such individuals should be minimised.

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<sup>10</sup> This phrase is used by Brownsword and it is explained later in this section

<sup>11</sup> House of Commons, Science and Technology Committee, *Human Reproductive Technologies and the Law* (2004-2005) at 22

<sup>12</sup> There are several articles which are referred to in the discussion of the pluralism and the bioethical triangle. They are as follows: Brownsword R, ‘Stem Cells and Cloning: Where the Regulatory Consensus Fails’ (2005-2005) 39 *New Eng L Rev* 535-571, Brownsword R, *Rights, Regulations and Technological Revolution*, Oxford University Press, New York, 2008, 101-131, Brownsword R, ‘Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the Dignitarian Alliance’ (2003) 17 *Notre Dame Journal of Law* 15-51, Brownsword R, ‘Regulating Human Genetics: New Dilemma for a New Millennium’ (2004) 12 *Medical Law Review* 14-39, Brownsword R, ‘Stem Cells, Superman and the Report of the Select Committee’ (2002) 65 *Modern Law Review* 568-587, Caulfield T & Brownsword R, ‘Human Dignity: A Guide to Policy Making in the Biotechnology Era?’ (2005) *Nature* 72-76



Brownsword explains each of the three constituencies as follows. The first is the utilitarian constituency, human welfare, which is dedicated to the maximisation of health, wealth and happiness. He explains that it is the maximisation of utilities and the minimisation of disutilities which are of importance to this constituency, with utilities comprising of 'pleasure, preference, satisfaction, convenience and economy' and disutilities comprising of 'pain, suffering, distress, anxiety, frustration of plans, non satisfaction of preference, cost, inconvenience and expenditure of resources'.<sup>13</sup> Article 4 of the UNESCO Declaration illustrates this; it provides:

... direct and indirect benefit to patients, research participants and other affected individuals should be maximised and harm should be minimised ...<sup>14</sup>

The second human rights/ rights led constituency is founded on the respect for the inalienable and intrinsic dignity of humans. It prioritises the importance of individual interests, including free and informed consent, respect for autonomous decision making as well as the protection of privacy and confidentiality.

The third constituency is the relatively new dignitarian/ duty driven constituency. Drawing on the mixture of Kantian, Catholic and communitarian credos,<sup>15</sup> this constituency's fundamental principle is that human dignity should not be compromised and any practice that compromises human dignity is considered unethical irrespective of welfare-maximising consequences.

Brownsword explains that every constituency has its distinctive characteristics.<sup>16</sup> Dignitarians are opposed to both utilitarianism and human rights theorists; they disagree with utilitarians in that they do not believe that 'consequences, even entirely beneficial consequences ... are determinative' and they disagree with the human rights constituency as they do not share the belief that informed consent

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<sup>13</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 37

<sup>14</sup> Australia's 'National Statement on Ethical Conduct in Human Research 2007' has elements of utilitarianism as discussed in Chapters 4 to 6 of this thesis

<sup>15</sup> Utilitarianism and human rights tension prevailed in much of the second half of the twentieth century whereas the dignitarian alliance emerged in recent years. For more information about the emergence of the dignitarian alliance, see Brownsword R, 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the Dignitarian Alliance' (2003) 17 *Notre Dame Journal of Law* 15-51

<sup>16</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 35-41

permits and condones the compromise of human dignity.<sup>17</sup> Between utilitarianism and human rights theorists, there is tension as utilitarianism promotes the maximisation of utilities whereas human rights theorists impose some limitations/constraints in order to promote individual rights.<sup>18</sup> However, Brownsword notes that some overlap exists between dignitarians and human rights theorists on the basis that the theory of human rights is premised on the principle of human dignity. The difference is that dignitarians focus on human dignity but not on individual autonomy.<sup>19</sup>

In the context of the ethics of HESC research, there is little consensus among the three groups. As Brownsword explains, both utilitarian and human rights constituencies believe that HESC research is a field of major medical importance, provided that embryos do not suffer or are not deemed to have rights and that egg donors donate their eggs on the basis of free and informed consent.<sup>20</sup> However, dignitarians hold firmly and strictly to the view that human cloning, whether for reproductive or therapeutic, compromises human dignity and thus should be prohibited. They condemn cloning and HESC research; their condemnation operates as a ‘conversation stopper.’<sup>21</sup>

In the context of harm, even in pluralistic communities, according to Brownsword, there is widespread support for the general principle ‘Do no harm to others’ and that the interests of ‘the others’ should be respected.<sup>22</sup> The famous English philosopher, John Stuart Mill, is the greatest proponent of this principle.<sup>23</sup> It provides guidance to regulators, suggesting that the sovereignty of individual choices should be respected so long as the acts are not harmful to others. Therefore, regulators should not limit freedom unless the actions are considered harmful to others. However, in pluralistic

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<sup>17</sup> Ibid at 39

<sup>18</sup> Ibid at 38

<sup>19</sup> Ibid at 69

<sup>20</sup> Ibid at 36-39. The objection that egg donors will be exploited is both dignitarian as well as human rights objection against the instrumentalisation of women and their gametes. But with informed consent, this will cease to be an issue with human rights theorist but not with dignitarianism

<sup>21</sup> Ibid at 39

<sup>22</sup> For this section on the discussion of harm and the bioethical triangle, the main source is Brownsword R, ‘Cloning, Zoning and the Harm Principle’ 527-542 in Mc Lean S (ed), *First Do No Harm: Law, Ethics and Healthcare*, Ashgate, Aldershot, 2006

<sup>23</sup> Mill J, ‘On Liberty’ in Mill J, *Utilitarianism*, Fontana Press, London 1962

societies, there are different interpretations as to both the concept of ‘harm’ and the notion of ‘others’ among the three different constituencies.

First, utilitarians associate harm with disutilities like pain and suffering, distress and anxiety.<sup>24</sup> They do not object to the termination of the early development of a mere blastocyst, that is a 100-cell human embryo, on the basis that the embryo experiences no pain and suffering at that early stage of embryonic development. As for the concept of ‘others’, utilitarians interpret the word to mean beings who are capable of experiencing pain and suffering. For this constituency, at that point of development the embryo has not developed to fit in the category of beings capable of feeling any pain.

Human rights theorists interpret harm by reference to the ideals of the concept of human rights.<sup>25</sup> With informed consent, they consider that rights-holders have the capacity of authorising actions that would involve a violation of rights, and so, human rights-holders are the relevant others. However, human rights theorists disagree about the stage at which a foetal life attains rights-holding status. They argue that a 100 cell human embryo, in such an early stage of development, is not regarded as a rights-holder on the basis that it will be a long time before it has the capacity of active participation in a community of rights. Accordingly, the harm principle offers no reason to prohibit HESC research. However, Brownsword raises an indirect argument:

the implication that members of communities of rights have responsibilities that go beyond their individual obligations to one another and their collective support for public goods and that as stewards, they owe it not only to one another but also to future generations to pass on sustainable conditions.<sup>26</sup>

He is of the opinion that this idea merits further consideration.

Finally, the dignitarian’s interpretation of the harm principle is that harm is interpreted as any act that compromises human dignity.<sup>27</sup> ‘Others’ is understood ‘individually, collectively and inclusively as members of the community.’ The

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<sup>24</sup> For this section, the source is Brownsword R, ‘Cloning, Zoning and the Harm Principle’ at 538

<sup>25</sup> Ibid

<sup>26</sup> Ibid at 539

<sup>27</sup> Ibid

embryo is considered as an other as it is instrumentalised. They argue that this is a procedure that is harmful to the embryo which is one of the others, thus violating human dignity.<sup>28</sup>

The views of these three groups are difficult to reconcile. The greater the plurality of views in a society, the more challenging it is for regulators to strike positions that are recognised as legitimate by every constituency. It is inevitable that, under such conditions of pluralism, there will continue to be divergent views about the ethics of HESC research.<sup>29</sup> This is not unlike the classic contentious subjects of abortion and euthanasia where questions of life and death arouse deep emotions.

In Malaysia the different constituencies are also comprised of various religious groups.<sup>30</sup> Brownsword believes that religious constituencies, with their deep religious beliefs, compound the difficulties. He stresses that while these people do have one thing in common, that is, they are anxious to do the right thing, they have different views about some fundamental questions. He explains:

When you bring together a society of different religious constituencies, there are going to be differences that will really go deep. ...those constituencies whose views did not prevail are going to easily accept the position. They are still going to think that their view is the right view.<sup>31</sup>

He further explains that this challenge is a difficult one to resolve:

I believe that a decent/ rational case to be made for a set of values in a community of rights. It's the most defensible form of political association. But those with religious conventions and commitments, they are going to think they are right as well. And there is no reason to be tolerant of 'their views' because 'I'm right'. We've got to have some sort of process but I don't think the process would have a reasonably satisfactory resolution. Regulators try to calculate what their community want at an acceptable level of risk but that would not suit everybody.... the process may have some real conviction that it is the best we can do. If we use the process to resolve deep moral divisions, that's much more problematic. To get these process/ model to work, we have to bring people to the table ... If we expect them to set aside

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<sup>28</sup> Ibid at 539

<sup>29</sup> With reproductive cloning, there is consensus reached nevertheless

<sup>30</sup> See Chapter 7 of this thesis which explores the perspectives of different religions. Empirical data were gathered from the interviews conducted with the religious representatives of the main religions in the country

<sup>31</sup> Brownsword was responding to my question on his views of the challenge of enacting legislation on HESC research in multi-religious societies like Malaysia

their fundamental values, that seems unreasonable. The reason to bring them to the table is because they have differences.<sup>32</sup>

As Brownsword points out, the challenge of achieving regulatory legitimacy is compounded in societies where the different constituencies also comprise of various religious groups with their respective deep religious beliefs. The next section attempts to address this challenge.

#### *Addressing the first challenge*

In democracies, differences could be settled by reasoned debates. As Michael Kirby explains:

The very process of consultation and public debate promote a broad community understanding of the issues, an appreciation of different viewpoints and an acceptance of any regulation adopted, even when they give effect to conclusions different from one's own.<sup>33</sup>

In Australia there are consultative mechanisms such as the Australian Law Reform Commission (ALRC)<sup>34</sup> and independent inquiries such as the Lockhart Legislation Review Committee Report (the Lockhart report).<sup>35</sup>

While it is not reasonable to expect religious leaders to set aside their deep religious differences at open forums, that some provisional resolutions may possibly be achieved. As Brownsword says, 'in a community of rights, the only solution is to find some process/ proceduralism ... We have to have deliberative democracy<sup>36</sup> ... this is probably the best we can do.' He continues, 'It is the procedure that is crucial; such procedure is a hallmark of a democratic society. And regulators need to gather as much consensus as possible ...'<sup>37</sup> He cautions that the policy may be a provisional one that still leaves open for debate and it has to be a 'continuing

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<sup>32</sup> In an interview with Brownsword, 18 November 2009, London

<sup>33</sup> Kirby M 'New Frontier' in Brownsword R & Yeung K (eds), *Regulating Technologies*, Hart Publishing, Oxford & Portland, 2008, 367-388 at 387

<sup>34</sup> The Australian Law Reform Commission (ALRC) is an independent federal statutory authority that reviews Australia's laws to ensure that they are equitable, modern, fair and efficient. The ALRC conducts extensive consultations with the legal profession, interested organisations and the community to inform its research. See <http://www.alrc.gov.au/> (12 June 2010)

<sup>35</sup> The extent of consultations of this review committee is explored in Chapter 4, 5 and 6 of this thesis

<sup>36</sup> Deliberative democracy is a system of political decision-making that relies on consultation to make policy and legitimate lawmaking can arise only through public deliberation

<sup>37</sup> In an interview with Brownsword, 18 November 2009, London

dialogue' that cannot just 'close off', and he argues that this kind of political resolution is a better way than a violent conflict.

It is interesting that Braithwaite too expresses a similar opinion on the appropriate approach in dealing with dissenters. He says:

In a community of persuasion, in a meeting of minds, the scientists may agree to disagree. Some may say "I really disagree with the rules but I agree the rules have been reached by fair process which I have a fair opportunity to express my objections. This is a democracy; the democracy has decided or the court has decided that we live in a society of rule of law. I happen to think that it's not a particularly smart law but I want to comply with the rule of law.... When there is angry defiance, there's a need for regulators to sit down with the angry persons and try again and again to persuade them. There's a need for principled engagement with even the biggest renegade ... It's about dynamic of persuasion .....It's actually a principled thing about democratic conversation and how it should work so that people are brought to live together on the basis of agreeing to disagree.<sup>38</sup>

It is therefore important that in Malaysia reasoned debates and open forums are conducted to explore the issues fully. There are religious groups, such as the Department of Islamic Advancement of Malaysia/ Jabatan Kemajuan Islam Malaysia (JAKIM) that represent Muslim's interests, and MCCBCHST (Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism) representing other faiths.<sup>39</sup> These groups should be invited to present their respective religious interpretations and views on HESC research in open forums. While Malaysia is a multi-religious country, it is officially an Islam country and majority of its population is Muslim.<sup>40</sup> The Islamic interpretation of ensoulment is liberal, thus HESC research would not raise strong objections.<sup>41</sup> As for other religions such as Buddhism, Hinduism and Sikhism, there have been no official stands taken on the ethics of HESC research. The only religion that has expressed strong objections on the research is the Catholicism.

Attempting to resolve differences of religious interpretations in multi-religious Malaysia is and will remain a challenging task in reaching a consensus in the ethics

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<sup>38</sup> Brownsword was responding to my question about renegade scientists who are disposed not to comply with the law

<sup>39</sup> See Chapter 7.7 of this thesis

<sup>40</sup> This is provided in Article 3 of the Federal Constitution of Malaysia. 60.4% of its population is Muslims

<sup>41</sup> For its religious position on HESC research, see Chapter 7.2 of this thesis

of HESC research. However, as both Brownsword and Braithwaite argue, it is essential that there is some process/ procedure that ensures all voices are heard. While the outcome might be provisional, ‘the dialogue must not just close off’. With fair and open processes to produce regulatory outputs, regulators should invite regulatees to respect the regulatory regime since good faith regulatory settlements should be respected.

### **3.2.2 THE SECOND CHALLENGE: ACHIEVING REGULATORY EFFECTIVENESS**

Brownsword explains how regulators achieve regulatory effectiveness when their intervention works:

to be beyond reproach ... a regulatory intervention must be backed by legitimate regulatory purposes, and the regulatory means employed must be both morally clean and effective.<sup>42</sup>

Setting a threshold of regulatory effectiveness is particularly challenging. As Brownsword explains, if the bar is set at a level of complete control, then virtually all regulatory interventions are said to be ineffective. If the bar is set at a much lower level, ‘the regulatory intervention is declared effective when the ex post state of affairs merely represents an improvement over the ex ante situation’ (similarly, if they make any contribution, however small, to the reductions in the number of crime).<sup>43</sup>

Enforcement of regulation presents a further challenge. Professor Loane Skene raises these questions:

Is there an Act to create a whole regime with the requisite administrators, police and infrastructure and all the costs of that process? If there is a large group of renegade scientists and doctors want to do this, we could justify this.<sup>44</sup> Do we want to send a team of scientific police into laboratories to investigate and prosecute their activities? Do we want to impose criminal

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<sup>42</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 132

<sup>43</sup> Ibid

<sup>44</sup> A determined Italian doctor, Severino Antinori, has openly said in a press conference that he would attempt to experiment on reproductive cloning. It is therefore not surprising if there are other equally determined scientists who would want to attempt to conduct therapeutic cloning research

penalties on our best and brightest scientists and doctors who are striving to find new tools of diagnosis and therapy? <sup>45</sup>

There are three key sources of regulatory weakness according to Brownsword.<sup>46</sup> He explains:

The first key point lies with the regulators themselves.... the problem they could be captured/ corrupted or the problem of not getting the right advice or the problem of not getting sufficient resources.<sup>47</sup>

Powerful and influential regulatees could corrupt the agencies that are responsible for implementing the regulation. In the business world, this may be a realistic assessment of how some business is actually conducted but among scientists and researchers, it is less likely to be the case. However, it is difficult to ascertain how rampant corruption is (if it exists at all). However, there is no doubt that regulatory agencies are vulnerable in that they can be captured and dominated by powerful regulatees.

The second key source of the problem lies with regulatees. Brownsword says:

These are the people who don't want to comply. Professions like the medics, the scientists, the lawyers ... have their own internal codes that they think set the right kind of standard.

The third key source is 'some externality/ external disruptive influence like the global financial crisis that just knocks the regulation sideways'. He continues:

When we're thinking about regulatory effectiveness, we need to look at these three key nodes. In a larger picture, we need to think about these ... as to why regulation won't work. The answer is going to lie in one of the three ...

#### *Addressing the second challenge*

It is important to recognise that full compliance with the law is an unrealistic ideal and the fact that a law cannot be fully enforced is not by itself a good reason to reject it. Fukuyama refers to the example of murder, which is a crime and yet murders still occur. He explains that the fact murders occur has never been a reason

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<sup>45</sup> Skene L & Gogarty B, 'Stem Cell Research and Cloning: Legal Loopholes' (2002) *Australasian Science* 31-35

<sup>46</sup> These three key sources of weakness are elaborated in his article, Brownsword R & Somsen H, 'Law, Innovation and Technology: Before We Fast Forward-a Forum for Debate' at 23-25

<sup>47</sup> In an interview with Brownsword where he explained further on these three key sources of regulatory weakness



for giving up on the law or on attempts to enforce it. He raises a question whether homicide laws are judged to be effective only if they succeed in putting an end to murders or if they significantly reduce the number of murders.<sup>48</sup>

Various proposals may assist in attaining regulatory effectiveness. First, Brownsword made reference to Professor Stuart Biegel's principal regulatory guidelines with respect to the effective regulation of cybertechnology.<sup>49</sup> Being generalised, these guidelines are potentially applicable in the context of HESC research regulation. Brownsword explains that Biegel's guidelines can be summarised in two main points: First, regulators should act on the basis of consensus because they perform better when they act with the backing of regulatees rather than without it. He stresses that:

The important thing is that regulatees take ownership in the matter. It will be effective if they are involved on the groundwork and if no work has to be done. It is not going to take ground, it's only going to be any good when the groundwork is prepared in the way that the regulatees are already disposed to act in this way. For example, in England when the ban on smoking in public places was introduced and it has been very effective... By the time the enactment took place, the public was already by and large disposed not to smoke... It's really endorsing a situation already in practice. So the extent in which the regulatees have been brought on board is very important... The real challenge is where there's no disposition to act in this way, where there's real resistance on the ground. ...One of the paradoxes of the law is that it works very well, it works very effectively when it has no work to do.<sup>50</sup>

The roots of the regulatee resistance may be economic, cultural, professional or moral in nature. As Braithwaite points out, 'while regulations can enforce minimum standards, they cannot enforce common sense and social responsibility'.<sup>51</sup> Thus, the regulatees who internalise the regulations and their purpose will outperform those who mechanically apply the prescribed standards without internalising the spirit.

Brownsword explains that the second main point of Biegel's guidelines is that regulators should adopt Braithwaite's 'responsive regulatory theory'.<sup>52</sup> He suggests

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<sup>48</sup> Fukuyama F, *Our Posthuman Future* Picador, New York, 2002

<sup>49</sup> Brownsword R, *Rights, Regulation and Technological Revolution* at 146-148

<sup>50</sup> In an interview with Brownsword, 18 November 2009, London

<sup>51</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 148

<sup>52</sup> Ibid

that regulators should strive for regulatory intelligence/ smart responsive regulation, which advocates a mix of different regulatory instruments.<sup>53</sup>

Another strategy to attain regulatory effectiveness is to assign inspectors to monitor licensees' compliance with the law. The Australian regulatory framework on cloning and stem cell research includes this feature.<sup>54</sup> Brownsword agrees that:

the inspectorate system might achieve regulatory effectiveness. It is a natural feature of a regulatory regime ... having set the standard, you then have to monitor and an inspection is what you do. You will expect inspection to be part of the package. Then the question is will this guarantee compliance, to which the answer is no.<sup>55</sup>

He cautions that an inspection system is no guarantee of compliance.<sup>56</sup> He refers to three scenarios. The first is where the regulatory regime requires the inspector to give prior notice before the day of inspection, as opposed to making random visits. The notice enables preparations to be made before the audit is conducted. Secondly, where regulators face a lack of resources, the number of inspections could be limited. The third scenario is where frequent inspections are conducted. A cosy relationship between the inspector and the researcher might develop and thus the inspector is said to be 'captured' by the regulatee. While these three scenarios raised suggest that monitoring compliance by inspectors does not guarantee regulatory effectiveness, it is nevertheless a natural feature and important to include such monitoring as part and parcel of the package of the regulatory system.

To achieve regulatory effectiveness, Brownsword summarised the key points as follows:

Regulators should consider the necessity for making an intervention, that they need to be clear about their objectives and smart in their approach, and that the more that regulators are able to act with the grain of regulatees' values, the more likely it is that their intervention will be effective.<sup>57</sup>

In addition, it is recommended that establishing a system of monitoring compliance by inspectors also achieves regulatory effectiveness.<sup>58</sup>

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<sup>53</sup> This important theory is further elaborated under sub-heading 3.3 of this chapter

<sup>54</sup> See Chapter 6.6 of this thesis

<sup>55</sup> In an interview with Brownsword, 18 November 2009, London

<sup>56</sup> Ibid

<sup>57</sup> Brownsword R, *Rights, Regulation and Technological Revolution* at 143

<sup>58</sup> In the interview, Brownsword agrees with this view

### 3.2.3 THE THIRD CHALLENGE: MAINTAINING REGULATORY CONNECTION

As new technologies develop rapidly, regulatory frameworks may lose connection with the technological state of the art. Brownsword explains that this causes a mismatch, leading to a regulatory crisis.<sup>59</sup> When regulatees do not know with certainty where they stand, a fundamental principle of the Rule of Law is violated—that the current regulatory position should be communicated clearly by regulators to regulatees. A regulatory void causes regulatees to face uncertainties and encounter challenges in interpreting the legal position. As a consequence, they face a difficult choice: either they assume that their acts are permitted or they assume these acts are prohibited. This uncertainty is unsettling especially for law abiding regulatees.

If and when a particular case goes to court, judges are faced with a choice. Brownsword explains that they could adopt a literal form of statutory interpretation, that is, to interpret and apply the law as declared on the face of the legislation. Alternatively, they could apply a more creative purposive approach, that is, they can seek to be creative and make an attempt to reconnect the law to the modern technology, focusing on the underlying purpose of the legislation. Either approach is problematic.<sup>60</sup> While the literal approach fulfils the principle of congruence,<sup>61</sup> it leaves a regulatory void until the legislature reconnects the law to the technology.<sup>62</sup> If the court adopts the creative purposive approach, it might then be able to reconnect the law. But, this breaches the principle of congruence that is central to the ideals of the Rule of Law.<sup>63</sup>

Brownsword refers to the UK's *Human Fertilisation and Embryology Act 1990* as a classic example of a statutory definition which no longer corresponds with the technological state of the art.<sup>64</sup> An English case, the *R v Secretary of State for*

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<sup>59</sup> For this argument by Brownsword, see Brownsword R, *Rights, Regulation and Technological Revolution* at 160

<sup>60</sup> Ibid

<sup>61</sup> The principle of congruence is Fuller's eighth constitutive elements of legality; the principle of the administration of law should be congruent with the rules as promulgated.

<sup>62</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 161

<sup>63</sup> Ibid

<sup>64</sup> Ibid at 168-183

*Health ex parte Quintavalle (on behalf of Pro-Life Alliance)/ (Quintavalle case)*,<sup>65</sup> this case illustrates the disconnection between this Act and the new technology of SCNT. The facts are as follows. An action was brought against the Human Fertilisation Embryology Authority (HFEA) by Josephine Quintavalle, a campaigner for the Pro-life Alliance. The Pro-Life Alliance, which opposes any form of embryo destruction, sought a declaration that embryos created by SCNT do not fall within the ambit of *Human Fertilisation and Embryology Act 1990*, which regulates the use and creation of embryos in the UK. The main argument was that these organisms created by the new technology did not fall within the definition of 'embryo' in the Act. In the High Court, the challenge was successful but on appeal, it failed before both the Court of Appeal and the House of Lords.

Section 1(1) of the Act provides that an embryo is a live human embryo where fertilisation is complete. The question arises as to whether the Act applied to embryonic clusters and how the prohibition related to such developments. The Pro Life Alliance argued that the Act did not cover a SCNT embryo because it did not have the same properties, namely the combination of haploid cells and that did not go through the process of fertilisation. The High Court, adopting a literal approach, held that the Act applied only to human embryos produced by a process involving fertilisation. In his speech, Justice Crane said that he was compelled to consider only the intention of the government in 1990 rather than present day government, and therefore declined an invitation to attempt to rephrase any sections of the 1990 Act to make them apply by analogy to organisms produced by SCNT.<sup>66</sup> The restrictive wording precluded his lordship from including what Parliament had not foreseen or intended.

However, the Court of Appeal<sup>67</sup> and House of Lords<sup>68</sup> reversed, by adopting a creative purposive approach in order to make a reconnection. They held that such embryos fell within the ambit of 1(1) albeit they were not produced by fertilisation.

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<sup>65</sup> *R v Secretary of State for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2001] 4 All ER 1013 (Quintavalle)

<sup>66</sup> Quintavalle, paragraph 57

<sup>67</sup> *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* [2002] QB 628 (Quintavalle appeal 1)

<sup>68</sup> *R v Secretary of State for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2003] UKHL 13 (Quintavalle appeal 2)

The Court of Appeal found that although the original drafters of the legislation did not intend to include SCNT embryos, it did not strain the language of the statute to breaking point to include them.<sup>69</sup>

In the House of Lords, Lord Bingham in his leading speech said that fertilisation in 1(1) could not have been intended to signal a difference between human embryos produced by natural fertilisation of an egg by sperm and human embryos created by SCNT technology since Parliament could not have contemplated at the time that the latter technology was possible.<sup>70</sup> He said the crucial point was that ‘... this was an Act passed for the protection of live human embryos created outside the human body and ... The essential thrust of section 1(1)(a) was directed to such embryos, not the manner of their creation ...’<sup>71</sup> The appellate courts relied heavily on Lord Wilberforce’ speech in the case of *Royal College of Nursing of the United Kingdom v Department of Health and Social Security*<sup>72</sup> where he said:

In interpreting an Act of Parliament, it is proper and indeed necessary to have regards to the state of affairs existing and known by Parliament to be existing at the time ... where a new state of affairs or a fresh set of facts bearing on policy, comes into existence, the courts have to consider whether they fall within the Parliamentary intention. They may be held to do so, if they fall within the same genus of facts as those to which the expressed policy has been formulated. They may also be held to do so if there can be detected a clear purpose in the legislation which can only be fulfilled if the extension is made ... There is one course which the courts cannot take, they cannot fill gaps ...<sup>73</sup>

On an important note, Lord Wilberforce stressed that what the courts must not do is to gap-fill and second-guess the intention of Parliament.

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<sup>69</sup> (Quintavalle appeal 1) para 27

<sup>70</sup> (Quintavalle appeal 2) para 14

<sup>71</sup> Ibid

<sup>72</sup> [1981] AC 800. Other articles referred to in the discussion of this case are: Nicol D, Chalmers D & Gogarty B, ‘Regulating Biomedical Advances: Embryonic Stem Cell Research’ (2002) *Macquarie Law Journal*, 48-49, Gogarty B, ‘What Exactly is an Exact Copy? And Why it Matters When Trying to Ban Human Reproductive Cloning in Australia?’ (2003) *Journal of Medical Ethics* 85-86, Gogarty B & Nicol D, ‘The UK’s Cloning Law: A View from the Antipodes’ (2002) <<http://www.murdoch.edu.au/elaw/issues/v9n2/gogarty92.html>> (22 February 2010), Morgan D and Ford M, ‘Cell Phoney: Human Cloning after Quintavalle’ (2004) *Journal of Medical Ethics* 524-526, Brownsword R, ‘Stem Cells, Superman and the Report of the Select Committee’ (2002) 65 *Modern Law Review* 568-587

<sup>73</sup> [1981] AC 800 at 822

The equivalence between an embryo produced by natural fertilisation of egg by sperm and an embryo produced by SCNT technology persuaded the appellate courts to decide that if research on the former could be licensed under the Act, the latter too could be licensed. There is sound justification for this conclusion, on the basis that an SCNT embryo is a potential human being which is created and used as a tool for research. Therefore, the spirit of the regulatory scheme extends to the creation and use of these embryos in research. In the lead-up to the 1990 legislation, there was serious concern about permitting human embryos to be used for research purposes in UK and it is therefore argued that the appeal courts were right in suggesting that the Parliamentarians in 1990 would not have drawn a distinction between an embryo produced by fertilisation and one created without it.

If the appellate courts had decided that SCNT embryos fell outside the jurisdiction of the regulatory authority, then the regulatory position would have been that research on these embryos and reproductive cloning was unconditionally permitted. Before the Court of Appeal reached its decision, on 4<sup>th</sup> December 2001 the UK Parliament rushed through sui generis legislation to pass the *Human Reproductive Cloning Act 2001* to fill the legislative gap created by Crane J's decision.

The Quintavalle case is a clear illustration of the challenge of regulatory disconnection. Since the framework legislation was enacted in 1990 in the UK, embryology and its associated techniques have progressed. SCNT is a recent development and on a literal reading, the legislative language did not cover this new technology. The Act defined an embryo that assumed that it was the product of a natural process of fertilisation of egg by sperm. The development of SCNT caused the disconnection with section 1(1) of the Act, and Brownsword describes this case as one of 'descriptive disconnection'.<sup>74</sup> The appellate courts maintained connection by interpreting the regulation in a purposive way, treating the guiding spirit and intent of the legislation as more important than its letter. Brownsword supports such creative intelligent purposive interpretation as it did not threaten the principle of congruence and remained within the spirit and intent of the regulation.<sup>75</sup> However, his concern is that in other circumstances the purposive approach may breach of the

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<sup>74</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 166

<sup>75</sup> *Ibid* at 183 -184

rule of congruence which is central to the ideal of the Rule of Law, and warns that this approach should not be resorted to at all costs.<sup>76</sup>

### *Addressing the third challenge*

A range of strategies could be developed to improve the prospect of regulation staying connected to the ever-changing, evolving technology. Each strategy is explored below.

First, regulatory responses should be geared for flexibility and adaptability. As illustrated in the Quintavalle case, if the draftsmen had drafted technology neutral language in the statute, this would have enabled judges to take the literal interpretation and still maintained regulatory connection. For instance, draftsmen could use language such as ‘any means of human reproduction.’

The UK Parliament’s expedition in enacting the *Human Reproductive Cloning Act 2001* demonstrates that legislatures have the capacity to respond rapidly to new technological developments when they see fit to do so.

Secondly, it is important to undertake a review of the law within a reasonable time frame after the enactment of the legislation or after the enactment of the amended legislation. In Australia, s47A of *RIHE Act 2002* requires a review of the statute be undertaken three years after its enactment.<sup>77</sup> This is evidenced in 2005 when the Lockhart committee was formed to review the 2002 Act on cloning and stem cell research in the light of latest scientific developments. It received many oral and written submissions.<sup>78</sup> At the conclusion of 2010, there will be a similar legislative review of the *Amendment Act 2006*. Conducting reviews of the law is an attempt to keep the law connected to the changing technology. The Australian experience has

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<sup>76</sup> Ibid

<sup>77</sup> This clause provides that the Minister must cause a further independent review of the operation of Act in three years after *the Amendment Act 2006* comes into effect. This is in line with Recommendation 53 of the Lockhart Report. In comparison, in the UK, the 1990 Act was amended only in 2008

<sup>78</sup> See Chapter 4.8 of this thesis. The Lockhart committee was set up in 2005 to review the 2002 legislations

been a positive one and as illustrated in the Lockhart review where there was thorough review of the legislations relating to cloning and stem cell research.<sup>79</sup>

Third, it is important that the recommendations resulting from reviews of the law see swift implementation. Concerns have been raised about legislative logjams and adapting legislative time-table. As Brownsword explains, the challenge of the Parliamentary time-table leads to the ‘roller coaster’ effect and the issues ‘swing back and forth’.<sup>80</sup> In the UK, a fast track system to implement the Law Commission reports was adopted when the *Legislative and Regulatory Reform Act* was passed in 2006. The Act allows a minister, by ministerial order, to implement recommendations of the Law Commission. In any event, the Australian experience is a positive one; the Amendment Act was passed just one year after the release of the Lockhart report, where in the majority of its recommendations were implemented.

These strategies should be used to ensure the law is kept up to date and remains connected with the ever changing, evolving technology.<sup>81</sup> It is especially important, following the Australian experience, that law review is conducted within a reasonable time frame after enactment of the legislation and that its recommendations are implemented. These strategies will assist in maintaining regulatory connection.

### **3.2.4 THE FOURTH CHALLENGE: REGULATORY COSMOPOLITANISM<sup>82</sup>**

One aspect of the challenge of regulatory cosmopolitanism is the critical problem of ‘stem cell tourism’. This is where desperate persons, especially the very ill who live in countries where stem cell based medical treatments are not available, travel

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<sup>79</sup> The Lockhart Report reviewed both 2002 legislations

<sup>80</sup> In an interview with Brownsword, 18 November 2009, London

<sup>81</sup> In face of rapidly changing technology, the Lockhart Report raised three recommendations, 50, 51 and 52, that would give the NHMRC Licensing Committee power to make binding rulings in the interpretation of the legislation on certain conditions. See Chapter 4.10.8 of this thesis

<sup>82</sup> Kiatpongsan S & Sipp D, ‘On Stem Cell Travel and the Need for Clinical Trials’ (2008) *Genetics Policy Institute* 1-4, Kiatpongsan S & Sipp D, ‘Monitoring and Regulating Offshore Stem Cell Clinics’ (2009) 323 *Science* 1564-1565, Sipp D, ‘Stem Cell Research in Asia: A Critical View’ (2009) *Journal of Cellular Biochemistry* 1-4



elsewhere to seek such treatments. Some types of stem cell based treatments are already available in some developed and developing countries.<sup>83</sup> These stem cell based treatments are experimental and most of them are unregulated.<sup>84</sup> There are patients who are prepared to travel and pay a high price to seek these treatments.<sup>85</sup> Companies offering these services advertise the procedures on websites, YouTube and blogs.<sup>86</sup> Some of these clinics are even supported by their local government, regulatory agencies and medical associations.<sup>87</sup> There have been reports of baseless claims of cures,<sup>88</sup> charlatans<sup>89</sup> and adverse medical events including deaths.<sup>90</sup>

Stem cell tourism is important to the economies of some developing countries, which may thus be resistant to prohibitions by law. Different countries have different notions of ‘right’ and ‘wrong’ and state sovereignty dictates that no state can enforce its laws on another. As Brownsword explains, it is a challenge if a regulatory approach of a nation attempts to dictate local standards to another nation, that is, where ‘it seeks to steam roller over local culture and difference.’<sup>91</sup>

A study conducted by Professor Timothy Caulfield and his team analysed 19 websites advertising so-called stem cell therapies.<sup>92</sup> The study noted that these direct advertisements made to patients via the internet were easily and readily accessible. The study found that therapies were offered by privately operated clinics around the world including China, Turkey and Ukraine and the average costs were US\$21,500 excluding travel and accommodation for patients and their care-givers. The authors assessed whether the claims made on the websites were substantiated

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<sup>83</sup> These nations include Austria, the Netherlands, India and Thailand

<sup>84</sup> See Kiatpongsan S & Sipp D, ‘On Stem Cell Travel and the Need for Clinical Trials’

<sup>85</sup> Ibid

<sup>86</sup> Kiatpongsan S & Sipp D, ‘Monitoring and Regulating Offshore Stem Cell Clinics’ (2009) 323 *Science*, 1564-1565 at 1564

<sup>87</sup> Ibid

<sup>88</sup> Abbott A, ‘Doctors Accused of Doing Illegal Stem-cell Trials’ (2008) *Nature* <http://www.nature.com/news/2008/080430/full/453006a.html> (22 June 2010)

<sup>89</sup> Ibid

<sup>90</sup> Coghlan A, ‘Deaths Revive Warnings about Rogue Stem Cell Clinics’ (2010) *New Scientist* <http://www.newscientist.com/article/dn19056-death-revives-warnings-about-rogue-stemcell-clinics.html> (22 June 2010)

<sup>91</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 157

<sup>92</sup> Lau D, et al, ‘Stem Cell Clinics: The Direct-to-Consumer Portrayal of Stem Cell Medicine’ (2008) *Cell Stem Cell* 591-594. They conducted a Google search using the search phrase ‘stem cell therapy’ and the result was that there were 19 websites that made claims of stem cell based treatments

by reports published in the medical literature and found that most of these clinics overpromised results and underestimated the potential risks of the medical treatments they offered. Thus, the Caulfield study indicates that stem cell tourism is a serious and critical problem.

#### *Addressing the fourth challenge*

The challenge of regulatory cosmopolitanism is that regulation confined within national borders cannot ever be fully effective in controlling stem cell tourism. While it is acknowledged that stem cell tourism is a difficult issue, there are several ways, non-legal as well as legal, to address it.

Recognising the serious risks to human health and welfare posed by stem cell tourism, the scientific community and advocacy groups have begun to respond to the problem by formulating guidelines for doctors and scientists engaged in the clinical translation of stem cell research. The International Society of Stem Cells Research (ISSCR)<sup>93</sup> developed the *Guidelines for the Clinical Translation of Stem Cells (ISSCR Guidelines)* in 2008. The ISSCR's objective is to provide guidance on the proper and responsible translation of stem cell research into safe and appropriate applications.<sup>94</sup> By way of recommendations to institutions, review committees and investigators, best practice standards to be observed in translational preclinical applications of stem cell technology are established. These *ISSCR Guidelines* provide comprehensive guidance for the future development of responsible stem cell therapies from research to clinic and in the following paragraphs, the various recommendations in the *ISSCR Guidelines* that deal with the problem of stem cell tourism are explored.

First and foremost, it is important to create awareness amongst researchers embarking on stem cell based clinical research of the existence of the *ISSCR Guidelines* as well as other policies and regulation. According to Recommendation 1, adequate steps should be taken by the research institutions where preclinical or

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<sup>93</sup> The ISSCR is an independent, non-profit organisation established in 2002 to foster the exchange of information on stem cell research

<sup>94</sup> The guidelines are available on <http://www.isscr.org/about/index.htm> (11 June 2010). The guidelines were developed by the task force for the Clinical Translation of Stem Cells, a multidisciplinary group of stem cell researchers, clinicians, ethicists and regulatory officials from 13 countries

clinical research involving stem cells is performed to ensure that their researchers are aware of the Guidelines and other regulations. In addition, these institutions should also ensure that the guidelines are put into practice by the researchers.

The Guidelines also emphasise that all clinical research should be reviewed with rigour. Recommendation 2 provides that this task lies with the institutional human subjects review committees, with the assistance of experts where necessary. In countries without such expertise, the ISSCR notes that it will assist in the identification of the experts.

The Guidelines confirm that voluntary informed consent of patients involved in clinical trials is the cornerstone of clinical research and it is imperative that such consent is properly obtained and overseen by the human subjects research committee.<sup>95</sup> Consent of the patient is of particular importance in highly innovative interventions. The Guidelines recommend that in the context of stem cell clinical trials, patients must be informed of the source of the cells,<sup>96</sup> that the stem-cell derived products have never before been tested in humans and that accordingly researchers do not know whether they will work in humans<sup>97</sup> and finally, that cell-based interventions may lead to adverse effects, possibly for the life time of the patient. Patients who initially provide consent to participation but later change their minds should be allowed to withdraw from the research. According to Recommendation 30, withdrawal from participation is permitted and it should be conducted in an orderly manner that would promote physical and psychological safety of the patient.

Recommendation 20 lists the various important obligations imposed on stem cell-based clinical researchers. In particular, it states that researchers should share their scientific expertise with other investigators and human subjects research review

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<sup>95</sup> Recommendation 28

<sup>96</sup> As Caulfield's study shows, some sources of stem cells are from animals such as sheep; see Lau D et al, 'Stem Cell Clinics: The Direct-to-Consumer Portrayal of Stem Cell Medicine' at 591. Even if the source of cells are from human, the research subjects still need to know whether they are adult or embryonic

<sup>97</sup> Animal models of a number of diseases are not accurate reflection of human diseases and toxicological studies in animals are sometimes unreliable at predicting toxicity in humans. Also, in transplantation studies where human cells are implanted in animals, it does not provide an accurate prediction of immune or other biologic responses in humans; see page 4 of *ISSCR Guidelines*

committees. They should address the risks of stem cell-based interventions and monitor their research subjects for long-term health effects with a ‘clear, timely and effective plan for adverse event reporting’. Medical treatment for toxicity such as tumour formation should be provided and researchers should also seek insurance coverage or other financial or medical resources for the research subjects to cover any medical complications that may occur from their research participation.

Other recommendations in the *ISSCR Guidelines* recognise the importance of monitoring and reporting of adverse incidents,<sup>98</sup> transparency and publication of negative as well as positive results,<sup>99</sup> and public engagement in policy making.<sup>100</sup> Recommendation 37 provides for regular review and revision of the Guidelines, recognising the dynamic nature of the science of stem cell research and the need for regulatory connection as propounded by Roger Brownsword. It is also pertinent to note that Recommendation 22 strongly encourages the establishment of regulatory bodies to monitor researchers and clinicians involved with stem-cell based products in all countries where such research and clinical trials are undertaken, with professional advice and support from ISSCR.

While it is recognised that the foregoing are merely guidelines and countries have no obligation to follow them, they are nevertheless important and valuable.<sup>101</sup> According to Insoo Hyun, the *ISSCR Guidelines* are intended to provide a benchmark for researchers in clinical trials in less regulated nations and ‘the hope is that the guidelines will prompt governments to adopt appropriate regulations ...’<sup>102</sup> He is of the view that ‘the guidelines lay out definitions for what constitutes an above-board clinical centre and provide consensus on stem-cell procurement and therapeutic standards.’ However, others have expressed contrary opinions about the

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<sup>98</sup> Recommendation 29

<sup>99</sup> Recommendation 33

<sup>100</sup> Recommendation 37

<sup>101</sup> It is also the opinion of Professor Donald Chalmers that the *ISSCR Guidelines* are commendable; see Chalmers D, ‘Stem cell technology: From Research Regulation to Clinical Applications’ in Campbell A (ed), *Bioethics and the Global Politics of Stem Cell Science: Medical Application in a Pluralistic World*, World Scientific, 2010 (forthcoming). Professor Roger Brownsword shared the same view (in an interview, 18 November 2009, London). n

<sup>102</sup> Baker M, ‘Stem Cell Society Condemns Unproven Treatments’ (2008) *Nature Reports Stem Cells*. Insoo Hyun is the co-chair of the ISSCR task force and a bioethicist at Case Western Reserve University in Cleveland, Ohio

effectiveness of the *ISSCR Guidelines*. For example, Wise Young opines that the Guidelines would not stop clinics that are already in breach of medical ethics from providing misleading information. Furthermore, he is of the view that the Guidelines are not likely to influence a patient's decision whether to travel to receive the medical treatment at his/ her own risk.<sup>103</sup>

Despite the negative views expressed by some commentators as to the value of the *ISSCR Guidelines*, it is submitted here that they are an important preliminary step in raising the awareness of the international community about these critical issues. Recognising the seriousness of the challenge of stem cell tourism and with the professional support offered by ISSCR, it is argued that local regulators in nations with less developed regimes for the regulation of research and clinical trials should, as a matter of urgency, establish effective national regulatory frameworks to strictly oversee all stem cell research and stem cell based clinical trials conducted within their national boundaries.

### 3.3 RESPONSIVE REGULATORY THEORY<sup>104</sup>

An effective regulatory framework for HESC research in Malaysia should be responsive. The theory of responsive regulation was originally conceptualised by Professor Ian Ayres and Professor John Braithwaite in 1992.<sup>105</sup> This theory proposes that 'regulators should be responsive to the conduct of [regulatees] [before] deciding whether a more or less interventionist response is needed'.<sup>106</sup> The first response to proscribed behaviour is to determine how effectively individuals or corporations self-regulate before deciding whether to escalate intervention. Giving primacy to less invasive responses facilitates this approach<sup>107</sup> and 'attempts to solve the puzzle of when to punish and when to persuade.'

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<sup>103</sup> Ibid

<sup>104</sup> This section relies heavily on Braithwaite J, *Regulatory Capitalism*, Edward Edgar Publishing, Cheltenham & Northampton, 2008, 88-139

<sup>105</sup> Ayres I & Braithwaite J, *Responsive Regulation*, Oxford University Press, New York/ Oxford, 1992

<sup>106</sup> On these explanations of the fundamentals of the theory, see *Regulatory Capitalism* at 88

<sup>107</sup> Braithwaite explains that what motivated him and Ayres to formulate this theory is due to the frustration with the 'see sawing' in policy making between two groups of people; on one hand, a group who argues that business people only understand the bottom line and therefore must be punished for lawbreaking and on the other hand, a group who claims that business people are responsible people who can be persuaded to comply with the law

The most distinctive part of responsive regulation is the Braithwaite's regulatory pyramid (see Figure 1) with each increment step increasingly demanding in its sanctions. The pyramid illustrates the ideal that less punitive measures should be the reaction of first instance. At the base of the pyramid, self-compliance is encouraged. The wide base of the pyramid represents the majority of cases that are handled informally, restorative dialogue-based approach. They are non-punitive responses, that is, they are based on persuasion as well as self-regulation. The narrowing towards the top of the pyramid illustrates the increasingly fewer cases handled by progressively more formal means. Moving up the pyramid, the regulations are increasingly demanding in their sanctions. The inexorability of escalation to punitive responses is the key to influencing human behaviour. Regulators will be able to move up and down the pyramid to access the appropriate level of regulation necessary.

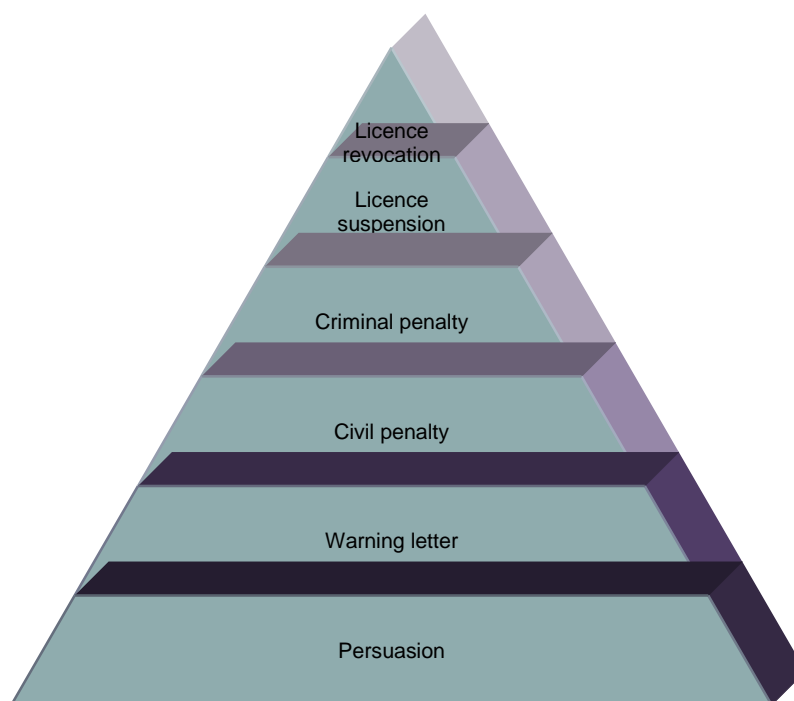


Figure 1: An example of Braithwaite's enforcement pyramid in the context of a business

As an example, at the base of the pyramid, attempts are made to encourage compliance of the law by persuasion. If this fails, the next step is to issue a warning letter; if this fails to secure compliance, civil monetary penalties are imposed. If this fails, criminal prosecution ensues and penalties like fine will be imposed, if this

fails, the licence to operate is suspended and this fails, arriving at the peak of the pyramid, the licence to do business is revoked and the business must cease.

According to responsive regulatory theory, a ‘spectre of punishment [is] threatening in the background but never threatened in the foreground’.<sup>108</sup> The theory claims that if persuasion by itself is to work, stiffer forms of consequences must loom as a real and likely threat. The main point is that the peak of the enforcement pyramid creates downward pressure which causes the majority of the action to occur at the base of the pyramid, that is, in the realms of persuasion and self-regulation.<sup>109</sup> The existence of the capacity to get as tough as is needed can bring about a regulatory culture which is more voluntaristic and less litigious. Braithwaite warns that if the top of the pyramid is lopped off, there will be less prospect of self-regulation and persuasion as an alternative to punishment.<sup>110</sup> The greater the heights of punitiveness to which a regulatory agency can escalate, the greater its capacity to push regulation down to the base of the enforcement pyramid.<sup>111</sup> A truncated pyramid with a truncated range of escalations will exert less downward pressure to keep regulation at its base than a tall pyramid whereas a tall enforcement pyramid can be used to apply great pressure from the heights of its peak to encourage voluntary compliance.<sup>112</sup>

Braithwaite refers to the regulatory agencies as ‘the Benign Big Guns that walk softly while carrying very big sticks’,<sup>113</sup> that is, while regulators have great powers, they rarely ever use the power of criminal prosecution. Compliance is optimised by regulation that is both tough and forgiving. Forgiveness is advocated for its importance in building commitment to comply in future and punishment is about deterrence. As Braithwaite explains, ‘Paradoxically, the bigger and the more various are the sticks, the more regulators will achieve success by speaking softly’.

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<sup>108</sup> See Braithwaite J, *Regulatory Capitalism* at 94

<sup>109</sup> Braithwaite J, ‘Convergence in Model of Regulatory Strategy’ (1990-1991) 2 *Current Issues Criminal Justice* 59-65 at 64

<sup>110</sup> Ibid

<sup>111</sup> Ibid at 65

<sup>112</sup> Ibid

<sup>113</sup> Ibid at 59

The second pyramid is the Braithwaite's 'strengths-based pyramid' as illustrated in figure 2. It is a pyramid of responses to individuals and organisations. This pyramid of support promotes a virtue whereas the pyramid of regulatory strategies restrains vice. Thus, it has features of the provisions of incentives rather than the imposition of punishments. The idea of this pyramid is that as it moves up, it moves to targeting progressively higher rewards on progressively smaller target groups. Starting at the base, strategies are minimally interventionist and minimally costly, yet have the relevance to the widest possible community.<sup>114</sup>

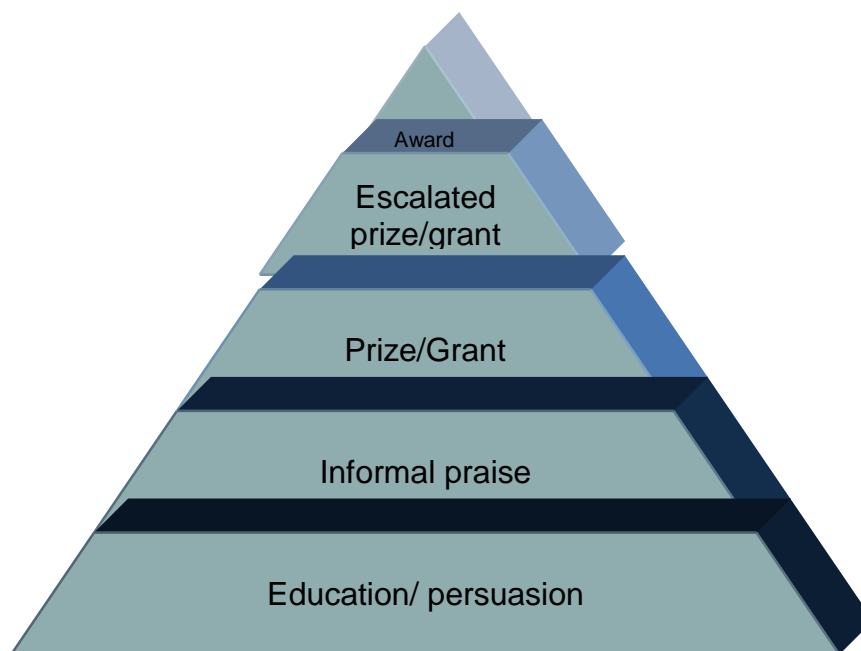


Figure 2: A possible approach of a Braithwaite's pyramid of strengths-based pyramid to motivate conduct

Responsive regulatory theory suggests that 'regulators should operate with a cooperative default approach'<sup>115</sup> and attempt to seek win-win relationships with their regulatees. They will perform 'well to respond to non-compliance in a way that leaves room for escalating sanctions, for flexibility, and for sensitivity to the nature and character of particular regulatees.'<sup>116</sup>

<sup>114</sup> Braithwaite J, *Regulatory Capitalism* at 109-139

<sup>115</sup> Brownsword R, See *Rights, Regulation and Technological Revolution* at 138

<sup>116</sup> Ibid



Brownsword recommends the application of Braithwaite's responsive regulatory theory to achieve regulatory effectiveness.<sup>117</sup> He asserts that:

there is no point in reinventing the wheel ... We do have some general regulatory intelligence. It is not as though observers of the regulatory process have detected no recurring patterns (relatively speaking) in regulatory failure and regulatory success ... we can carry forward the principal insights of smart regulatory theory, namely that traditional criminal law interventions cannot be counted on to control in the way that regulators intend, that regulators have at their disposal a range of instruments that might be deployed to channel and control conduct and that regulators would do well to seek out the particular combination of instruments that most effectively promote their particular regulatory purposes.' While these insights are important in steering regulators away from interventions that are likely to be futile or even counter-productive, we are ... short of a comprehensive and reliable regulatory jurisprudence (with settled precedents) pointing to the particular combinations of instruments that are appropriate for particular cases.<sup>118</sup>

### **3.3.1 THE APPLICATION OF RESPONSIVE REGULATORY THEORY IN THE CONTEXT OF HESC RESEARCH**

The thesis is informed by these two pyramids in the context of regulating HESC research in Malaysia. Both pyramids are complementary. 'Pyramid design is a creative, deliberative activity'<sup>119</sup> and 'regulators that think responsively tend to design very different kinds of pyramids for different kinds of problems ...'<sup>120</sup> The first pyramid of regulatory strategies designed in this thesis is illustrated in Figure 3 below.

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<sup>117</sup> In interview with Brownsword, 18 November 2009, London

<sup>118</sup> See Brownsword R, *Rights, Regulation and Technological Revolution* at 137

<sup>119</sup> Braithwaite J, 'Responsive Regulation and Developing Economies' (2006) 43 *World Development* 888

<sup>120</sup> Ibid

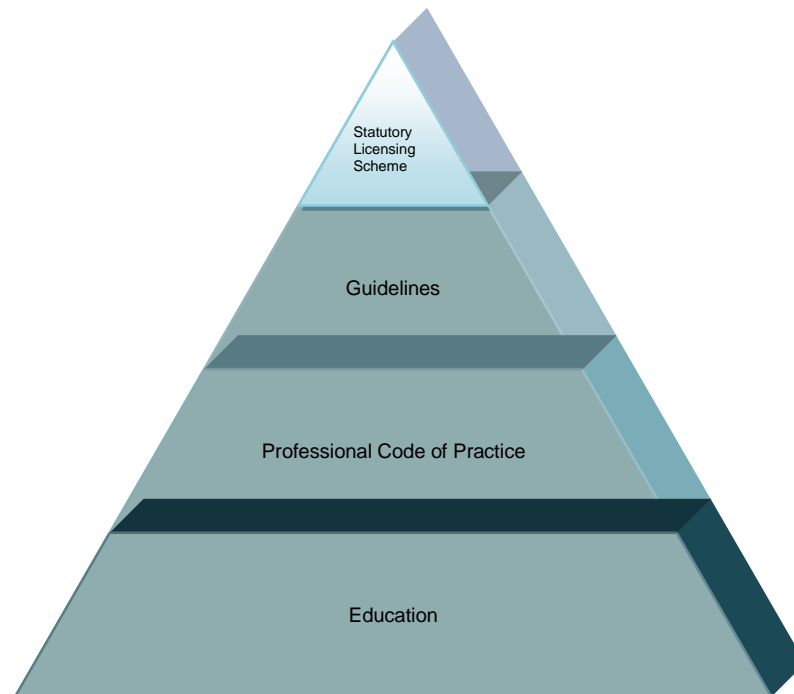


Figure 3: A possible approach of a pyramid of regulatory strategies to regulate HESC research

At the base of the pyramid is education. Through education, awareness is created amongst the scientific community about the importance of observing high ethical standards whilst conducting HESC research and the consequences of breaching the regulation. It will be seen later in this thesis that the Australian regulatory framework includes this important component.<sup>121</sup> It is based on a model of ‘cooperative compliance’ where licence holders are encouraged to cooperate with the NHMRC to comply with the legislation. Emphasis is placed on education and communication, as these promote awareness of the responsibilities of both licence-holders and inspectors. A key mechanism for raising such awareness is through information exchange visits, which were made to researchers, licence-holders, human research ethics committee members and other interested organisations. In addition, information is made available through seminars, workshops, websites and publications. In this way, researchers are deterred from breaching the law.

On the next rung of the pyramid is professional Code of Practice/ industry self regulation, the aim being to provide guidance as well as support and advice to

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<sup>121</sup> See Chapter 6.6 of this thesis

scientists. Professional bodies and institutions should adopt industry self-regulation. This practice is encouraged as it sets industry standards for compliance. However, it is noted that a reservation of the model of self-regulation is that it may be seen as a licence for self-interested regulatory activity, that is, an industry may act in ways that suit its own interests and sets regulatory standards as long as it is happy to comply with those standards.

Further up the pyramid is the Guidelines scheme, also known as soft law/ under legislation, made by government agencies.<sup>122</sup> Guidelines are advantageous in the regulation of new technologies. They are flexible and can be amended as needed. Amendments can be made slowly, focusing directly on issues that arise as new discoveries are made.<sup>123</sup>

Finally, at the apex of the pyramid is statutory licensing scheme where restrictive research on embryos is permitted by statute and criminal offences apply where the activity is carried out without a valid licence.<sup>124</sup>

With the strengths-based pyramid model (Figure 2), scientists are motivated to be compliant with regulations. At the base of the pyramid, through education, scientists are informed and motivated to conduct research whilst observing high ethical standards. On the next rung is receiving an informal praise and not everyone is singled out for a special praise. This is followed by receiving prize/ research grant and again not everyone will receive the grant. The next rung is ‘escalated’ prize/ grant and few will receive, for instance, a \$1m dollar grant. Finally at the peak of the pyramid, even fewer will receive an award such as the Nobel prize or being conferred knighthood or being named as the ‘Person of The Year’ and receiving cash prize.

A regulatory model which includes both regulatory and strengths-based pyramids, comprises of the two pyramids, is effective as it has a combination of instruments

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<sup>122</sup> For instance, the NHMRC guidelines in Australia

<sup>123</sup> Countries that have adopted national guidelines scheme as their regulatory model include USA, Japan, India, China, Spain and Malaysia

<sup>124</sup> UK, Sweden, New Zealand, Canada, Finland, Greece, Israel, the Netherlands, Singapore, South Korea, the American states of California and New Jersey

that promote the regulatory purposes with a spectre of punishment in the background. Thus they have the effect of channelling/ controlling the conduct of scientists. In the words of Braithwaite, 'It's very important to have a mix of support and sanctions.'<sup>125</sup>

It may be argued that the theory of responsive regulation might not be appropriate in some regulatory arenas and it is acknowledged that the theory of responsive regulation is an approach designed in wealthy developed countries. As Ayres and Braithwaite explain, the theory is 'not a clearly defined program or a set of prescriptions concerning the best way to regulate' and therefore, it should not be mechanically applied as the appropriate strategy to be adopted would 'depend on the context, regulatory culture and history.'<sup>126</sup> It is recognised that a limitation that the developing world faces is the lack of capacities necessary to make responsive regulation work effectively compared to wealthy societies. In Malaysia, the potential challenges include the high costs that are likely to be incurred and the need for well-organised extensive training as well as broad public education and engagement.<sup>127</sup> It is conceivable that these difficulties are particularly acute in developing nations. But this does not mean that responsive regulation is any less desirable in poorer countries. Rather, it should be of universal application. As Braithwaite explains :

Responsive regulation deals with the fact that no government has the capacity to enforce all laws. It is useful for thinking about regulation in developing countries with weak enforcement capabilities.<sup>128</sup>

As such, Braithwaite's theory of responsive regulation is as relevant to Malaysia as to any other country. The potential challenges that Malaysia regulators might encounter as identified above could be effectively addressed with assistance from the ISSCR and by adopting model regulatory frameworks that have already been successfully implemented in countries like Australia, moulded to local needs. In this

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<sup>125</sup> In an interview with Braithwaite, 19 October 2009, Canberra

<sup>126</sup> See Braithwaite J, *Responsive Regulation* at 5

<sup>127</sup> In Part II (Chapters 4-6) of this thesis, these factors are explored in the analysis of the Australian regulatory regime

<sup>128</sup> See Braithwaite J, *Responsive Regulation and Developing Economies* at 888. On the relevance and applicability of his theory in the developing world, Braithwaite refers to various examples such as the resolution of the 2006 East Timorese crisis, see Braithwaite J, *Regulatory Capitalism* at 100-108

regard, the regulatory regime adopted in Singapore, a close neighbouring country which has similar culture and political and legal institutions, is pertinent.<sup>129</sup> Today, this nation has one of the world's most permissive and progressive regimes for the regulation of HESC research alongside with UK and Israel.

### **3.3.2 TRIPARTISM AS A SOLUTION TO REGULATORY CAPTURE**

There is a risk that a regulatory policy that fosters cooperation between the regulator and the regulatee could encourage corruption. Brownsword has expressed his concern that regulatory agencies may be 'captured'/ bribed by some powerful and influential regulatees.<sup>130</sup> This is especially true where relationships between the parties are ongoing and encounters are repeatedly made by the same regulator. Corrupt dealings then become more tempting to both parties.

Braithwaite explains that any system could be corrupted but some are harder to corrupt than others. He refers to some examples where there are opportunities for corruption. He says, 'Elections could be fixed. You can corrupt the electoral officer and get him to count the votes wrongly' and he also gives the example of the grant of an Oscar academy award 'where every member of the academy gets a vote as to who shall win the Oscar, so there's the possibility of corruption.'<sup>131</sup>

As a possible solution to the serious risk of regulatory capture and corruption, Braithwaite advocates the concept of tripartism, a process involving a third player in the regulatory process, for instance, relevant public interest groups.<sup>132</sup> It fosters the participation of these groups by granting them access to all the information available to the regulator, a seat at the negotiating table with the regulatory agency and regulatee, and the authority to sue or prosecute. As Braithwaite explains:

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<sup>129</sup> See Chapter 8.8 of this thesis which explores the successful experience in Singapore, an exemplary model that the Malaysian government could emulate

<sup>130</sup> Brownsword R, *Rights, Regulation and Technological Revolution* at 138

<sup>131</sup> In an interview with Braithwaite, 19 October 2009, Canberra

<sup>132</sup> Braithwaite J, *Responsive Regulation* at 55-56

Solutions to the problems of capture and corruption - limiting discretion, multiple industry rather than single industry, agency jurisdiction and rotating personnel- inhibit the evolution of cooperation.<sup>133</sup>

Braithwaite refers to the example of the issue of a grant. He explains:

When you have a licensing board that gives grant, the committee does it rather than a bureaucracy and you have representatives. The government gives out research grants to universities but people who make recommendations to government are people who are experts from industry, from universities, from the government and they sit down as a committee to make a collective decision. It's much harder to bribe a committee than it is to an individual bureaucrat. If it's a bureaucracy giving out a grant, then all you have to do is to bribe the head of bureaucracy ... So you just have to corrupt one person but if it's a committee with people from outside the bureaucracy that are giving out the grants, then you can still bribe the committee but it's hard. One member of the committee isn't open to being bribed and blows the whistle on all the others. He/ she might find it morally offensive to take a bribe. And those who take a bribe fear that they may be in trouble. So the committee are protection against bribery just like juries in criminal cases. Juries are good institutions ... it's always easier to bribe a single judge than to bribe the whole jury. The judges are repeat players so they build a relationship and use that. Whereas with juries, this is the only case that they sit on with their whole lives and the investment in building that relationship does not bring much return. So it's harder to bribe a committee. The solution connects with tripartism which is having the third or fourth party involved in the process.<sup>134</sup>

It is noted that tripartism is an effective solution to the potential problem of regulatory capture/ corruption and it is therefore important to have multi-players in the field. As illustrated in Chapter Six of this thesis on the Australian licensing system, the composition of its Licensing Committee comprises of professionals from diverse background.

### 3.4 CONCLUSION

A fundamental issue raised in this thesis is whether to regulate HESC research and the response is in the affirmative. This leads to the enquiry as to whether the Australian model of regulation is an appropriate one for the Malaysian regulators to

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<sup>133</sup> Ibid at 54

<sup>134</sup> In an interview with Braithwaite, he referred to Indonesia's independent Corruption Eradication Commission/ Komisi Pemberantasan Korupsi (KPK) which he thinks was effective in controlling corruption in the country in the period 2005 -2008 and he also made brief reference of the success of the Hong Kong model

adopt. In this chapter, regulatory theory is explored and it is argued that it provides useful guidance in the design of an effective framework to regulate HESC research in Malaysia.

As Malaysian regulators move towards the formulation of a regulatory framework to govern HESC research, it is argued that, as a matter of best practice, they should take heed of the four principal challenges identified by Brownsword. While these challenges are difficult to resolve in the context of HESC research, this chapter recommended various steps that could be taken to address and mitigate these difficulties. While Malaysia is a diverse nation, regulatory legitimacy could still be achieved in a pluralistic society by conducting consultations and reasoned debates. Such debates have the potential to promote a broad community understanding of many issues, science and ethical issues. This will lead to an appreciation of different viewpoints and possibly an acceptance of regulations adopted even when they give effect to conclusions different from one's own. In Australia, consultative mechanisms like the Australian Law Reform Commission (ALRC) law reform inquiries and independent inquiries such as the Lockhart review<sup>135</sup> provide templates for Malaysia to emulate.

Regulatory effectiveness can be attained when regulators regulate with the grain, establish a stringent monitoring system and apply Braithwaite's responsive regulatory theory, which suggests a mix of different regulatory strategies. With the potentially serious problem of regulatory capture, the concept 'tripartism' advocated by Braithwaite is a possible effective solution.

Regulatory connection can be maintained if legislation is carefully drafted in general terms, using technological neutral language to enable judges to interpret legislation while observing the principle of congruence which is vital to the rule of law. In addition, undertaking law review within a reasonable time frame after enactment as well as swift implementation of the review's recommendations, would connect the law with the fast moving science.

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<sup>135</sup> See Chapters 4, 5 and 6 of this thesis

With the challenge of regulatory cosmopolitanism, specifically the area of stem cell tourism, it is argued that it is a matter of prudential calculation for individual patients. That this area remains as a major challenge for national regulators does not obviate a need to establish a national framework to regulate HESC research conducted within the borders of that country.

Braithwaite's responsive regulatory theory is potentially useful and influential in the design of a regulatory framework for Malaysia. While there are warnings that the theory may not effectively apply in some circumstances, it can still achieve success in the regulation of HESC research in this country. With the pyramid of strategies, emotional economy of shame and the strengths-based pyramid, emotional economy of pride, there is a range of instruments that inflict punishments as well as provide incentives. These instruments are employed to channel/ control the conduct of scientists involved in the field of HESC research. They will promote the regulatory purposes and the framework has a spectre of punishment in the background. Therefore, the design of the regulatory framework comprising of the two pyramids which is effective, is recommended for adoption by the Malaysian government.

In the next three chapters of this thesis, the proposed structure is tested using the Australian framework for the regulation of research involving human embryos in order to determine its application and effectiveness, before embarking on its possible application to the Malaysian context.



## **PART 2: THE REGULATORY REGIME FOR USE OF HUMAN EMBRYOS IN RESEARCH IN AUSTRALIA**

In determining the options for Malaysia in establishing an effective regulatory framework for HESC research, it is worthwhile to analyse the regulatory frameworks for HESC research in other countries with long and well established regulatory frameworks. The regulatory framework of Australia is a valuable comparator with a long record of regulating ART with the world's first legislation on ART, the *Infertility (Medical Procedures) Act*, introduced in 1984 in the state of Victoria.

Part 2 of the thesis contains three chapters, which explore and analyse the legislative position on embryo research, cloning and stem cell research in Australia. This Part aims to determine the extent to which Australia's regulatory model achieves regulatory legitimacy (Chapter 4), maintains regulatory connection (Chapter 5) and attains regulatory effectiveness (Chapter 6) as formulated by Brownsword. These questions are considered within the theoretical framework for assessing regulation, particularly biotechnology regulation, as formulated by Professor Brownsword, discussed in the previous chapter. In addition, this part of the thesis attempts to determine whether Australia's regulatory model also meets Braithwaite's pyramid test of responsive regulation, also discussed in the previous chapter. The important features of Australia's regulatory model analysed in Part 2 of the thesis are useful references for the Malaysian government in establishing a strict regulatory regime to govern HESC research in the country.

## 4: ACHIEVING REGULATORY LEGITIMACY: THE EVOLVING RESPONSIVE REGULATORY REGIME

### 4.1 INTRODUCTION

This chapter examines the extent to which the Australian regulatory model to regulate research involving human embryos achieves regulatory legitimacy. As explained in the previous chapter, regulatory legitimacy refers to the extent to which the regulatory position adopted in a society is judged by all constituencies in the society as acceptably legitimate and ethically appropriate.<sup>1</sup>

Differences of opinions may be settled by public consultations and, as Kirby explains, ‘the very process of consultation and public debate promote a broad community understanding of the issues, an appreciation of different viewpoints and an acceptance of any regulation adopted, even when they give effect to conclusions different from one’s own.’<sup>2</sup>

Furthermore, Brownsword explains that the greater the consensus regulators could gather from regulatees, the more likely they will achieve regulatory effectiveness, his second regulatory challenge. He says:

... the more that regulators are able to act with the grain of regulatees’ values, the more likely it is that their intervention will be effective.<sup>3</sup>

Australia is a pluralistic society consisting of people with different religious and moral values and this chapter examines whether public consultations have been conducted with attempts to balance the diverse views of the Australian society on contentious issues surrounding research involving human embryos. Conducting such consultations prior to the enactment of legislation or/ amending legislation, including issuing new guidelines or/ amendment of existing guidelines, provide evidence that regulatory legitimacy is achieved. In addition, compelling evidence of the achievement of regulatory legitimacy are Parliamentary debates as they

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<sup>1</sup> See Chapter 3.2.1 of this thesis

<sup>2</sup> Kirby M, ‘New Frontier’ in Brownsword R & Yeung K (eds), *Regulating Technologies*, Hart Publishing, Oxford & Portland, 2008, 367-388 at 387. Also see Chapter 3.21 of this thesis

<sup>3</sup> See the discussion in Chapter 3.2.2 of this thesis

provide an avenue for the conduct of formal and structured debates where contentious issues are fully explored and debated.

## 4.2 FROM EARLY DAYS TILL PRESENT

The regulatory framework of Australia on cloning and stem cell research has a lengthy record with the world's first legislation on ART introduced in 1984 in the state of Victoria. It is evolving, complex and responsive. This section traces an historical overview of the country's regulatory events, which include the following milestones:

- 1984: in the state of Victoria, the world's first legislation on ART, the *Infertility (Medical Procedures) Act*;
- 1996: the *Ethical Guidelines on Assisted Reproductive Technology (ART Guidelines 1996)*;
- 1998: 'Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings' report (AHEC Report);
- 1999: the *National Statement on Ethical Conduct in Research involving Humans (National Statement 1999)*;
- 2001: the 'Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research' report (Andrews Report) (2001);
- 2002: Together these reports led to the enactment of national legislation, that is, the *Prohibition of Human Cloning Act 2002 (Cth) (PHC Act 2002)* and the *Research Involving Embryos Act 2002 (Cth) (RIHE Act 2002)*;
- 2004: the *Ethical Guidelines on the use of Assisted Reproductive Techniques (ART) in Clinical Practice and Research (ART Guidelines 2004)*
- 2005: an independent mandated legislation review, the 'Legislation Review Committee Report' (Lockhart Report);
- 2006: *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Amendment Act 2006)* was passed;
- 2007: the *National Statement 1999* replaced with the *National Statement on Ethical Conduct in Human Research (National Statement 2007)*

- 2007: the *ART Guidelines 2004* were revised: the *Ethical Guidelines on the use of Assisted Reproductive Techniques in Clinical Practice and Research (ART Guidelines 2007)*
- 2007: the third set of NHMRC guidelines released: the *Objective Criteria for Embryos Unsuitable for Implantation (Objective Criteria)*; and
- 2011: an independent mandated legislation review, the ‘Report of the Independent Review of the *Prohibition of Human Cloning for Reproduction Act 2002* and *Research Involving Human Embryos Act 2002*’ (Heerey Report)<sup>4</sup>

From the summary above, it is evident that the continually evolving and responsive Australian regulatory regime on cloning and stem cell research maintains regulatory connection, in Brownsword’s theoretical framework, a point elaborated in the succeeding chapter. The following sections elaborate each historical milestone from the early days till present. These sections will also explore whether and to what extent public consultations were conducted prior to the making of the regulation. As mentioned, this question is crucial in order to determine whether and to what extent the Australian regulatory regime achieves regulatory legitimacy.

### 4.3 THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY

Victoria’s *Infertility (Medical Procedures) Act 1984*, based on three major reports presented to the Victorian Government by Professor Louis Waller,<sup>5</sup> was the first legislation on ART in the world.

In the early years, there was no nationally consistent legislation covering ART across Australia.<sup>6</sup> Three states, Victoria, South Australia and Western Australia,

<sup>4</sup> [https://legislationreview.nhmrc.gov.au/sites/default/files/legislation\\_review\\_reports.pdf](https://legislationreview.nhmrc.gov.au/sites/default/files/legislation_review_reports.pdf) (19 January 2012)

<sup>5</sup> Chalmers D, ‘Researching on Embryos: Australian Standards’ (2001) *Regulating the New Frontiers: A Symposium in Centre for Law and Genetics* 127

<sup>6</sup> National legislation was highly desired then but did not materialise. Chalmers D & Nicol D, ‘Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? (Part II)’ (2003) *Law and the Human Genome Review* 91-108 at 93

introduced legislation dealing with ART practice.<sup>7</sup> The legislation in those states included the following:

- Banned human cloning, although cloning was defined differently in each state, and prohibited certain practices;
- Regulated research involving embryos and gametes, that is eggs and sperm;
- Were mainly focussed on ART practice, providing regulation for aspects such as storage of embryos and their destruction after a set period which differed from state to state; and
- Prohibited research that destroyed or diminished the potential for an embryo to be re-implanted.

In Victoria, the original legislation had a strict regulatory system that included criminal penalties.<sup>8</sup> It was replaced by the *Infertility Treatment Act 1995* that introduced a licensing system for ART clinic and providers.<sup>9</sup> The South Australian and Western Australia legislation included similar licensing systems and codes of practice for ART providers that were marginally more permissive about research activities.<sup>10</sup>

The other states and territories did not introduce legislation. These other states and territories preferred to rely on and follow existing national guidelines. There were two sets of guidelines, the *NHMRC Ethical Guidelines on Assisted Reproductive Technology* (1996)<sup>11</sup> and the *National Statement on Ethical Conduct in Research Involving Humans* (1999).<sup>12</sup> These guidelines were national standards of acceptable practice, which were responsive to a rapidly changing technology. Infringement of the guidelines is not an offence but there are sanctions imposed on infringers which

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<sup>7</sup> The legislation in each state is as follows: *Infertility Treatment Act 1984, 1995* in Victoria, *Human Reproductive Technology Act 1991* in Western Australia, *Reproductive Technology Act 1988* and *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* in South Australia

<sup>8</sup> *Infertility Treatment 1984*

<sup>9</sup> This Act was later repealed by *Assisted Reproductive Treatment Act 2008*

<sup>10</sup> *Human Reproductive Technology Act 1991* in Western Australia, *Reproductive Technology Act 1988* and *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* in South Australia. In New South Wales, the *Assisted Reproductive Act 2007* was passed

<sup>11</sup> This was revised in 2007

<sup>12</sup> This has been replaced by *National Statement on Ethical Conduct in Human Research* in 2007

usually involve loss of access to research funds, whether NHMRC funding or other public funding, or being named in Parliament as an infringer.<sup>13</sup> These *ART guidelines* referred specifically to the special status of the embryo, and limited embryo experimentation to therapeutic procedures. These ART guidelines, according to the statutory requirement, were sent out for public consultations, prior to their publication as official NHMRC guidelines.<sup>14</sup>

These *ART guidelines* were accepted within the accreditation regulations of the Fertility Society of Australia. The society has a separately constituted and independent Reproductive Technology Accreditation Committee (RTAC), which accredits ART clinics. Accredited clinics must comply with the FSA code of practice, which requires compliance with the NHMRC guidelines. The Andrews' Report suggested that self-regulation of this nature may not be as effective as a statute-based regulatory framework because the RTAC is not sufficiently independent.<sup>15</sup>

As a consequence of the piecemeal approach across the country, the regulatory regime associated with embryonic stem cell technology in Australia was described to be 'messy and ambiguous'.<sup>16</sup> In the following section, after the creation of Dolly, the Australian government's response will be examined.

#### **4.4 THE SCIENTIFIC, ETHICAL AND REGULATORY CONSIDERATIONS RELEVANT TO CLONING OF HUMAN BEINGS**

In the 1990s new challenges emerged in research in assisted reproductive technology (ART) and human stem cells. The creation of Dolly, the sheep, in 1997 raised the possibility that cloning human beings might be technically feasible. This

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<sup>13</sup> Nicol D, Chalmers D & Gogarty B, 'Regulating Biomedical Advances: Embryonic Stem Cell Research' (2002) *Macquarie Law Journal* 44

<sup>14</sup> Sections 12-14 of *National Health and Medical Research Council Act 1992*

<sup>15</sup> Regulating Biomedical Advances: Embryonic Stem Cell Research' at 45. The AHEC, in letters to Federal Minister, expressed the view that the remaining State and Territories should introduce legislation complementary to that in the three states with ART legislation. The Andrews Report in paras 9.37-9.50 stated the nature of ART was too complex to be dealt with adequately by a non-statutory regime

<sup>16</sup> Chalmers D & Nicol D, 'Can the Law Balance Ethical, Scientific and Economic Values?' at 93

led to an increase in research interest in cells derived from human embryos. These scientific developments raised significant ethical issues about human reproduction and the types of ethically permissible research which use human embryos.

On November 2000 the Federal Minister for Health and Aged Care<sup>17</sup> requested the Australian Health Ethics Committee (AHEC) to advise him on the scientific and ethical consequences flowing from the Dolly report and whether there was a need for legislation on reproductive cloning of human beings. In response to the request, the AHEC established a Working Group.<sup>18</sup>

It is noted that the Working Group chose not to conduct formal public consultation because there were many national and international pronouncements from professional groups and community groups that indicated a consensus of opinion on the prohibition of cloning of human beings.<sup>19</sup> Secondly, the AHEC did not intend to publish guidelines. It is a statutory requirement that public consultations must be held prior to issuing the guidelines. However, a draft of the Working Group report was circulated to a wide range of people knowledgeable in the field, including scientists and ethicists, for comment.<sup>20</sup>

The Working Group report was presented to the full AHEC that published a report entitled 'Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Being' (AHEC Report).<sup>21</sup> It included chapters on scientific considerations and potential for human application of cloning technology,<sup>22</sup> ethical issues relevant to cloning,<sup>23</sup> Australian legislation and guidelines relevant to cloning,<sup>24</sup> international legislation and guidelines relevant to cloning<sup>25</sup> and recommendations and resolutions.<sup>26</sup>

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<sup>17</sup> The Minister was Hon. Dr Michael Wooldridge MP

<sup>18</sup> Professor Donald Chalmers was the WP chair and chair of AHEC at the time

<sup>19</sup> Letter to the Minister by the chair of AHEC, Professor Donald Chalmers

<sup>20</sup> Appendix 2 of AHEC Report

<sup>21</sup> This report was prepared in 1998 and was rescinded by the NHMRC on 18 September 2003

<sup>22</sup> Chapter 2 of AHEC Report

<sup>23</sup> Chapter 3 of AHEC Report

<sup>24</sup> Chapter 4 of AHEC Report

<sup>25</sup> Chapter 5 of AHEC Report

<sup>26</sup> Chapter 6 of AHEC Report

The report made four recommendations and two resolutions.<sup>27</sup> Its recommendations were as follows:<sup>28</sup>

- The Commonwealth government, through the Minister for Health and Aged Care, should endorse the UNESCO *Declaration on the Human Genome and Human Rights*, in particular Article 11, by determining appropriate measures for prohibiting certain practices contrary to human dignity such as reproductive cloning;
- Noting that three states, Victoria, South Australia and Western Australia, had legislation prohibiting reproductive cloning of human beings and regulating embryo research, the Minister for Health and Aged Care should urge the remaining States and Territories to introduce legislation to limit research on human embryos according to the principles set out in sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*;
- Noting that there are statutory authorities established in the three states which considered and might approve human embryo research under strict conditions, the Minister for Health and Aged Care should urge the remaining States and Territories to establish similar statutory authorities with power to regulate research on human embryos according to the principles set out in sections 6 and 11 of the NHMRC *Ethical guidelines on assisted reproductive technology*; and
- The Minister for Health and Aged Care should encourage as well as promote community discussion on the potential benefits and risks of the development of cloning techniques.

The resolutions were as follows:<sup>29</sup>

- Until legislation is introduced in the remaining States and Territories, AHEC should collect information from institutional ethics committee (IECs) on their research approvals of projects involving the application of cloning on techniques to human embryos; and

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<sup>27</sup> The recommendations and resolutions are at Chapter 6 of AHEC Report at 43-44

<sup>28</sup> The recommendations at 43 of AHEC Report

<sup>29</sup> The resolutions at 44 of AHEC Report



- The NHMRC should consider the establishment of an expert advisory committee to assist and advise the IECs on the scientific aspects of such research projects.

The AHEC Report was presented to the Minister for Health and Aged Care, who referred it to the Australian House of Representatives Standing Committee on Constitutional and Legal Affairs. This committee appointed Mr Kevin Andrews MP to chair a formal inquiry that took extensive public submissions. The subsequent report was entitled 'Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research' (Andrews Report).

#### **4.5 HUMAN CLONING: SCIENTIFIC, ETHICAL AND REGULATORY ASPECTS OF HUMAN CLONING AND STEM CELL RESEARCH REPORT**

The Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research Report (Andrews Report) proposed a framework for the regulation of human cloning and related research in Australia based on the NHMRC ART guidelines and the legislative regulation in Victoria, South Australia, Western Australia and the United Kingdom. The report proposed a regulatory framework with the following features:

- A national uniform legislative approach;
- Prohibition on human cloning for reproductive purposes and as a result of which any attempt to undertake cloning for reproductive purposes to be subject to criminal penalty and the withdrawal of a licence to undertake research in this area;
- A system of regulation for both privately and publicly funded research;
- Legislation regulating human cloning and stem cell research to be separate from that governing artificial reproductive techniques (ART);
- Research using cloning techniques be subject to clear legislative parameters including a complete ban on the deliberate creation of embryos for research purposes;

- A national licensing body be established to regulate human cloning and research using cloning techniques and individual researchers be licensed for each research project that involves the use of an embryo;
- A framework of principles for the import and export of embryonic stem cells; and
- A framework must be transparent, accountable and responsive.

It is noted that the committee received a total of 347 written submissions and 50 exhibits.<sup>30</sup> Two public forums were held as the Committee was keen ‘to bring together as many members of the scientific community, the church and community groups, ethicists and legal professionals as possible to explain and contest the array of views that were presented ... members of the public were able to participate directly in the collection of oral evidence at the forum by way of comment and questions to the witnesses.’<sup>31</sup> It is commendable that there was general public engagement as illustrated in their written submissions to the committee and in their participation in public forums. The involvements of the public leading to recommendations of the committee are evidence of regulatory legitimacy.

Following the recommendations of the Andrews Report, as endorsed by the Council of Australian Governments (COAG) in 2002, the federal Parliament passed two related pieces of legislation: (i) *the Prohibition of Human Cloning Act 2002* (Cth) and (ii) *the Research Involving Human Embryos Act 2002* (Cth).

#### **4.6 NATIONAL LEGISLATION PASSED IN 2002**

The *Prohibition of Human Cloning and Research Involving Human Embryos Bill* was introduced into the Australian Parliament in June 2002. After the initial debate, the Bill was split into two parts: *Prohibition of Human Cloning Bill* and *Research involving Human Embryo Bill*. The reason for the split was that there was

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<sup>30</sup> House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001) Canberra (Andrews Report) at 7

<sup>31</sup> Ibid

unanimous support for provisions prohibiting human cloning but considerable contention about proposed Bill regulating research involving embryos.<sup>32</sup>

The introduction of this legislation had been controversial and was subject to a conscience vote in the federal Parliament. Ultimately, both bills were passed with a clear majority in both houses. The combined effects of both Acts were to:

- Prohibit human cloning and several other practices considered acceptable;
- Prohibit the creation of human embryos, by any means, for any purpose other than for attempting to achieve a pregnancy in a woman; and
- Allow certain uses of excess human embryos created through ART under strict regulation and licence.

The main and obvious advantage of the enactment of legislation, compared to the adoption of mere guidelines, is that Parliament is arguably the best forum for the conduct of formal and structured debates where these contentious issues are fully explored and debated amounting to compelling evidence of regulatory legitimacy.

#### **4.6.1 MAIN PROVISIONS OF *PROHIBITION OF HUMAN CLONING ACT 2002***

Although the regulation of human cloning for reproductive purposes is not central of this thesis, cloning and stem cell research are often conflated. The differences between the two must be clearly drawn to understand the regulatory regime for cloning. Accordingly, the main provisions of the *Prohibition of Human Cloning Act 2002* (*PHC Act 2002*) need to be explored. The Act set out various prohibited practices. Division 1 contained the key provisions on the prohibition of human cloning. It made it an offence to intentionally:

- Create a human embryo clone (Section 9 of *PHC Act 2002*);
- Place a human embryo clone in the human body or the body of an animal (Section 10 of *PHC Act 2002*); and
- Import or export a human embryo clone (Section 11 of *PHC Act 2002*).

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<sup>32</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? (Part II)' at 94-96

It was not a defence to any charge laid in relation to these offences that the human embryo clone did not survive or could not have survived (Section 12 of *PHC Act 2002*). The maximum penalty for each offence was imprisonment for 15 years (Section 9-11 of *PHC Act 2002*).

Division 2 of the Act contained provisions on other prohibited practices. It was an offence to:

- Create a human embryo other than by fertilisation or developing such an embryo (Section 13 of *PHC Act 2002*);
- Create a human embryo for a purpose other than achieving pregnancy in a woman (Section 14 of *PHC Act 2002*);
- Create or develop a human embryo containing the genetic material provided by more than 2 persons (Section 15 of *PHC Act 2002*);
- Develop a human embryo outside the body of a woman for more than 14 days (Section 16 of *PHC Act 2002*);
- Use precursor cells from a human embryo or a human fetus to create a human embryo or develop such an embryo (Section 17 of *PHC Act 2002*);
- Make heritable alterations to genome (Section 18 of *PHC Act 2002*);
- Collect a viable human embryo from the body of a woman (Section 19 of *PHC Act 2002*);
- Create a chimeric or hybrid embryo (Section 20 of *PHC Act 2002*);
- Place a human embryo in an animal or in the body of a human or place an animal embryo in the body of a human (Section 21 of *PHC Act 2002*);
- Import, export or place a prohibited embryo (Section 22 of *PHC Act 2002*); and
- Trade in human eggs, human sperm or human embryos (Section 23 of *PHC Act 2002*).

The maximum penalty for the each offence was 10 years' imprisonment (Section 13-23 of *PHC Act 2002*).

It is noted that these provisions of the Act reflected the strong community objections in Australia, expressed during the Andrews' committee hearings and in

the submissions, to human reproductive cloning and related activities. These community objections to human cloning in Australia aligned with the general adverse opinion adopted in the international community. As Brownsword explains, in reproductive cloning, all three perspectives in the bioethical triangle arrive at a consensus as there are overwhelming concerns about safety and risks and this ‘three-way convergence is truly exceptional, more commonly, we find a two-way synthesis between utilitarianism and human rights thinking’.<sup>33</sup> As reflected in the provisions of the Act, the strong public opinion against human reproductive cloning was taken into consideration by Parliament. This was evidence of regulatory legitimacy as it amounted to a regulatory position considered by all constituencies in the Australian society as acceptably legitimate and ethically appropriate.

#### **4.6.2 MAIN PROVISIONS OF *RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002***

The second piece of legislation, the *Research involving Human Embryo Act 2002* (*RIHE Act 2002*), is the focus of this thesis and it set out a national regulatory framework for research on human embryos. The main object of the legislation was to address concerns about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by ART.<sup>34</sup>

The Act was passed with a comfortable majority in both Houses.<sup>35</sup> For the first time, it introduced a consistent national approach to research on human embryos in Australia, replacing the ‘messy and ambiguous’ state-based systems. It brought into alignment the ethical debate and legislative response to technology and embryo research. This Act was consistent with the AHEC Report 1998 and implemented the recommendations of the Andrews Report 2001 which were based on public consultations.<sup>36</sup>

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<sup>33</sup> Brownsword R, *Rights, Regulation and Technological Revolution*, Oxford University Press, New York, 2008 at 36

<sup>34</sup> Section 3 of *RIHE Act 2002*

<sup>35</sup> 99.33 in House of Representatives and 45:26 in Senate

<sup>36</sup> For details of the public consultation, see 4.5 of this chapter. On another note, under the Council of Australian Governments (COAG), the peak intergovernmental forum in Australia, comprising the Prime Minister, State Premiers, Territory Chief Ministers and the President of the Australian Local Government Association (ALGA), agreement of April 2002, all states and territories in Australia agree to introduce nationally consistent

The legislation created a national licensing scheme, separate from the continuing state-based regulation of ART, whereby researchers were licensed for each research project that involves use of an embryo. Its key feature was that the licensing regime is for the use of ‘excess’ ART embryos. Excess embryos were restricted to those embryos that have been created in order to achieve a pregnancy. Embryos could not be created for research. They had to be created for an intended pregnancy but which, after a period of frozen storage, were no longer needed for this purpose. For example, the embryos could have been excess because the couples have established their family. The aim of the Act was to allow research on human embryos but only in strictly limited circumstances.

Essentially, the legislation had three main provisions:<sup>37</sup>

- The use of a human embryo that was not excess ART embryo was prohibited for any purpose other than for the ART treatment of a woman to achieve a pregnancy, which must be carried out by an accredited ART centre;<sup>38</sup>
- The use of an excess ART embryo, including for research purposes, was permitted if authorised by a licence for the Embryo Research Licensing Committee of the NHMRC. These activities required proper consent from all responsible persons;<sup>39</sup> and
- The use of an excess ART embryo was allowed without a licence for certain exempt uses. ‘Exempt uses’ included storage, removal from storage, transport, observation, allowing the embryo to succumb and donation to another woman to achieve a pregnancy. In cases where the embryo was biologically unfit for implantation, exempt uses included diagnostic investigations by an ART centre that directly benefit the woman for whom

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legislation into their respective parliament. The *PHC Act 2002* and the *RIHE Act 2002 Act* do not exclude the operation of any state or territory laws but they provide a framework for concurrent operation of state or territory and Australian legislation. Since the introduction of *PHC Act 2002* and *RIHE Act 2002*, all states and Australian Capital Territory (ACT) have enacted revised or new legislation to reflect the national legislation

<sup>37</sup> The relevant sections of the legislation will be referred to later in the discussion

<sup>38</sup> An accredited ART centre is either a person or organisation accredited by the Reproductive Technology Accreditation Committee (RTAC) against the Code of Practice for Assisted Reproductive Technology Units (RTAC 2005), which is developed by the profession for the accreditation of the ART centres in Australia. Such centres, as well as public and privately funded research involving ART, are also expected to comply with National Health and Medical Research Council ethical guidelines

<sup>39</sup> The phrases are explained later in the chapter

the embryo was created in future attempts at conception. Such activities required consent in accordance with arrangements for the clinical practice of ART. All other activities or projects such as research, training or quality assurance activities required a licence.

The Act also laid down conditions for the use of human embryos that have been created by ART to help couples become pregnant. It distinguished between ART embryos that form part of an ongoing treatment programme and excess ART embryos.

An ‘excess ART embryo’ was defined as a human embryo:

- (i) that was created by ART, for use in the ART of a woman; and
- (ii) is excess to the needs of the woman for whom it was created and her spouse,<sup>40</sup> if any, at the time the embryo was created.<sup>41</sup>

In addition, an embryo can only be considered to be excess to the needs of the people concerned if there was written authority to this effect signed by both:

- (i) the woman for whom the embryo was created; and
- (ii) her spouse, if any, at the time the embryo was created.

Before an excess ART embryo was used as authorised by the licence, each responsible person must have given proper consent to that use and the licence holder must have reported in writing to the Licensing Committee that this consent had been obtained. ‘Responsible person’ was defined as:

- (i) each person who provided the egg or sperm from which the embryo was created;
- (ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy;
- (iii) any person who was the spouse of a person mentioned in paragraph (i) at the time the egg or sperm mentioned in that paragraph was provided; and
- (iv) any person who was the spouse of the woman mentioned in paragraph (ii) at the time the embryo was created.<sup>42</sup>

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<sup>40</sup> Spouse is anyone living with a person as their partner on a bona fide domestic basis

<sup>41</sup> Section 9(1) *RIHE Act 2002*

<sup>42</sup> Section 8 *RIHE Act 2002*

Consent of the parties was an essential preliminary requirement, before the Licensing Committee can begin consideration for the issue of a licence.

Initially, the use of excess ART embryos in research that may damage or destroy the embryo was restricted to those embryos created before 5 April 2002. This restriction lapsed on 5 April 2005 and thereafter, licensed researchers can use excess ART embryos.<sup>43</sup>

The Act established the Embryo Research Licensing Committee,<sup>44</sup> whose principal task was to license the use of excess ART embryos.<sup>45</sup> There were two stages to the issue of a licence. First, the Licensing Committee must be satisfied that all the required consents have been obtained<sup>46</sup> and the applicant had obtained approval for the activity or project by the Human Research Ethics Committee (HREC), in accordance with the NHMRC National Statement.<sup>47</sup> Secondly, the Licensing Committee was directed to have regard to the following matters in deciding where to issue the licence:<sup>48</sup>

- Whether the number of excess ART embryos is restricted to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
- The likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means;<sup>49</sup>

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<sup>43</sup> Section 46(a) *RIHE Act 2002*

<sup>44</sup> Section 13 *RIHE Act 2002*

<sup>45</sup> Section 20 *RIHE Act 2002*

<sup>46</sup> This might prove to be a significant hurdle for researchers according to Chalmers D and Nicol D. See 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? (Part II)' at 105

<sup>47</sup> Section 21(3) *RIHE Act 2002*. The issue is whether the Licensing Committee can or should look behind any such approval and investigate the decision-making process of the HREC according to Chalmers D and Nicol D. See 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? (Part II)' at 105

<sup>48</sup> Section 21(4) *RIHE Act 2002*

<sup>49</sup> The two matters, restricting the number of excess ART embryos and the likelihood of significant advance in knowledge, have the potential to provoke controversy between enthusiastic researchers and the Licensing Committee according to Chalmers D and Nicol D. See 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values? (Part II)' at 105. The Committee has only one member with expertise in



- Any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC;<sup>50</sup>
- The HREC assessment of the application; and
- Such additional matters as are prescribed by the regulations.

The Licensing Committee had broad powers to vary, suspend and revoke licences (Section 25 and 26 of *RIHE Act 2002*) and to monitor compliance (Part 3 of *RIHE Act 2002*). The Licensing Committee must maintain a publicly accessible database containing information on licences as well as licence conditions.<sup>51</sup> However, certain confidential information was protected from disclosure.<sup>52</sup>

The Act created a series of offences relating to the use of excess ART embryos without a licence. It was an offence to use an embryo that is not an excess ART embryo,<sup>53</sup> and to breach a licence condition.<sup>54</sup> Intention was an element of each of these offences. The seriousness with which the legislature views these offences was reflected in the penalties, with a maximum of five years' imprisonment.

The legislation did not regulate the use of human embryonic stem cells (HESC) once they have been derived under licence from an excess ART embryo. Guidance on this matter was provided by the NHMRC AHEC and overseen by institutional HRECs. In addition, research on adult and fetal stem cells was not affected by the legislation.

The detailed provisions of the Act addressed the serious concerns about scientific developments in relation to human reproduction and the utilisation of human

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a relevant area of research and others with expertise in reproductive technology. The Committee is able to seek additional expert advice from overseas experts

<sup>50</sup> The *RIHE Act 2002* has an associated regulation, the *Research Involving Human Embryos Regulations 2003 (RIHE Regulations 2003)* which prescribes the NHMRC guidelines that the LC must have regard to when issuing a licence. The guidelines are the *National Statement on Ethical Conduct in Research Involving Humans* (1999) (*National Statement 1999*), updated in 2007 and *Ethical Guidelines on the use of Assisted Reproductive Technology (ART) in Clinical Practice and Research* (2004) (*ART guidelines 2004*), updated in 2007. The third set of guidelines is the *Objective Criteria 2007*. All three guidelines are explored in the later part of this chapter

<sup>51</sup> Section 29 of *RIHE Act 2002*

<sup>52</sup> Section 30 of *RIHE Act 2002*

<sup>53</sup> Section 11 of *RIHE Act 2002*

<sup>54</sup> Section 12 of *RIHE Act 2002*

embryos by regulating activities that involved the use of certain human embryos created by ART.<sup>55</sup> They illustrated Brownsword's 'restrictive tilt' approach<sup>56</sup> where a licence applicant must follow before obtaining a licence to conduct research involving human embryos. They also illustrated the application of Braithwaite's theory of responsive regulation, incorporating a mix of two rungs of the pyramid of regulatory strategies: strict statutory licensing scheme and national guidelines. The next section explores the latter.

#### 4.7 NHMRC GUIDELINES

Guidelines are produced by the NHMRC to accompany the Act which set out steps, which clinicians and researchers should follow. While guidelines are not legally enforceable, failure to follow them may result in consequences that are enforced in law. The Licensing Committee will not issue a licence unless the activity proposed in the application was assessed and approved by an HREC constituted in accordance with and acting in compliance with the *National Statement on Ethical Conduct in Research Involving Humans* (1999) (*National Statement 1999*)<sup>57</sup> and the *Ethical Guidelines on the use of Assisted Reproductive Technology (ART) in Clinical Practice and Research* (2004) (*ART Guidelines 2004*).<sup>58</sup> The HREC ensures that the guidelines and protocol are fulfilled by the researcher.

The *National Statement 1999* contained Australia's primary guidelines for ethical conduct of research involving human participants. Its purpose was to promote ethical human research. Fulfilment of this purpose required that participants be accorded the respect and protection that is due to them. It involved the fostering of research that is of benefit to the community. The responsibilities set out in the *National Statement 1999* were intended to be consistent with the international human rights instruments that Australia has ratified. It was organised around values such as respect for human beings, research merit and integrity, justice and beneficence.

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<sup>55</sup> Section 3 of *RIHE Act 2002*

<sup>56</sup> Brownsword R, 'Regulating Human Genetics: New Dilemmas for a New Millennium' (2004) *Medical Law Review* 16 -17

<sup>57</sup> Section 21 of *RIHE Act 2002*. The *National Statement 1999* is now replaced by the *National Statement on Ethical Conduct in Human Research* (2007); see Chapter 5.6 of this thesis

<sup>58</sup> The *ART Guidelines 2004* were issued after both 2002 legislations were passed. These guidelines were revised in 2007

The second important set of guidelines was the *Ethical Guidelines on the use of Assisted Reproductive Technology (ART) in Clinical Practice and Research 2004* (*ART Guidelines 2004*).<sup>59</sup> Of relevance to this thesis was Part C, which provided ethical guidelines for research covering research involving embryos.<sup>60</sup> Section 15 contained general ethical guidelines for research including the following: respect all research participants (15.1), respect for human embryos (15.2), the research proposal must not include unacceptable or prohibited practices (15.3), minimise risks (15.4), offer separate decision-making processes (15.5), provide information to participants at their level of comprehension (15.6), obtain consent (15.7), keep detailed records (15.8), collect and report data on outcomes (15.9), assess and monitor outcomes for all participation (present and future) (15.10), disclose financial interests that the researcher may gain from the research (15.11) and respect conscientious objections raised by participants (15.12). Section 17 contained guidelines on the specific area of research involving excess ART embryos including the following: obtain a licence under the terms of *RIHE Act 2002* (17.12), ensure that the embryo has been declared an excess ART embryo under the terms of *RIHE Act 2002* (17.13), identify all persons responsible for the embryo under the terms of *RIHE Act 2002* (17.14), obtain proper consent under the terms of *RIHE Act 2002* (17.16), specify the purpose of the research (17.17), provide all relevant information to all persons responsible for the embryo (17.18), allow for the withdrawal of consent at any time (17.19) and keep accurate records about the source, use and outcome of each embryo used (17.20).

The *RIHE Act 2002*, together with the *ART guidelines* provided a comprehensive framework to govern research on human embryos in Australia. Both the Act and the guidelines illustrate the application of Braithwaite's theory of responsive regulation, incorporating a mix of two rungs of his pyramid of regulatory strategies.<sup>61</sup>

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<sup>59</sup> The 2004 ethical guidelines were issued after both 2002 legislations were passed. These guidelines were revised in 2007

<sup>60</sup> Section 15 at 63 – 65

<sup>61</sup> See Chapter 3.3.1 of this thesis. A mix of different regulatory strategies will assist in achieving regulatory effectiveness

#### **4.8 CORRESPONDING STATE AND TERRITORY LEGISLATION SUBSEQUENT TO THE ENACTMENT OF *PHC Act 2002* and *RIHE Act 2002***

Because the commonwealth legislation might not cover individuals who would then be able to challenge the constitutionality of any commonwealth legislation used to prosecute them, the states and territories agreed to introduce complementary legislation into their respective parliaments.<sup>62</sup> The introduction of the state legislation in the respective states and territories achieves consistency with the federal legislations. It is noted that the change in state and territory legislation was not undertaken immediately but took place over a number of years. The licensing committee reports to parliament trace the process of introduction of state and territory legislation.

#### **4.9 LEGISLATION REVIEW COMMITTEE REPORT AND THE CHALLENGE OF ACHIEVING REGULATORY LEGITIMACY IN AUSTRALIA**

A provision was included in each of the *PHC Act 2002* and the *RIHE Act 2002* for an independent review of the legislation after the second anniversary of the day it received the Royal Assent.<sup>63</sup> The provision laid down issues which the committee was to consider and report on. In addition, it specified that the review of the two Acts was to be undertaken concurrently by the same review panel. The Lockhart Report represented this independent legislation review. The Lockhart committee presented their report, which contained important and comprehensive review of the legislation relating to human cloning and research involving human embryos.

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<sup>62</sup> See the agreement on [http://www.coag.gov.au/intergov\\_agreements/docs/human\\_cloning.cfm](http://www.coag.gov.au/intergov_agreements/docs/human_cloning.cfm) (30 December 2011). The state legislations were as follows: *Research Involving Human Embryos* (New South Wales) Act 2003, *Prohibition on Human Cloning and other Prohibited Practices* (New South Wales) Act 2003, *Health Legislation (Research Involving Human Embryos and Prohibition of Cloning) Act 2003* (Victoria), *Research Involving Human Embryos Act 2003* (South Australia), *Prohibition of Human Cloning Act 2003* (South Australia), *Human Embryonic Research Regulation Act 2003* (Tas), *Human Cloning and other Prohibited Practices Act 2003* (Tas), *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* (Qld), *Human Reproductive Technology Amendment Act 2003* (WA), *Human Reproductive Technology Amendment (Prohibition of Human Cloning) Act 2003* (WA)

<sup>63</sup> Section 25 of *PHC Act 2002* and section 47 of *RIHE Act 2002*

On 17<sup>th</sup> June 2005, the Federal Minister for Ageing with portfolio responsibility for human cloning and stem cell research<sup>64</sup> appointed six members to be in the committee.<sup>65</sup> The committee was chaired by former Federal Court judge, the late Hon John Lockhart AO QC. The terms of reference for the review of both Acts were set out by the Acts. The following sections will elaborate the crucial issues raised in the Lockhart Report, starting with the challenge of achieving regulatory legitimacy in pluralistic Australia.

In the Lockhart Report, the committee stated that ‘the Australian society is made up of diverse communities, with different perspectives, interests and values ... the committee has accepted that some disagreements will remain.’<sup>66</sup> With such diversity, it is a challenge to achieve regulatory legitimacy.

As human cloning and research involving human embryos raised important questions of morality, social values, ethics, alleviation of human distress and scientific research, the committee is faced with a difficult task. Among the questions were:

- When does human life begin?
- How far should society allow research involving human embryos?
- What safeguards should surround the research?
- Should human embryos be accorded the same rights as human beings after both?
- How should ‘human embryo’ be defined?
- What safeguards should be provided to protect the rights of women?
- Can common ground be found between widely varying, indeed divergent, views of morality held by members of our society?
- Should society declare activities to be illegal, with all the attendant consequences of criminal conduct, when there is a wide range of ethical views on those activities?
- What are the limits of the use of in vitro fertilisation (IVF) and related methods (collectively known as assisted reproductive technology/ ART) and human embryo research?
- Should excess ART embryos continue to be available for research, with permission under licence?

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<sup>64</sup> The Federal Minister of Ageing was Hon Julie Bishop

<sup>65</sup> The six members were Professor Barry Marshall, a Nobel prize winner, Professor Loane Skene, a lawyer and ethicist who stepped in to chair the Committee after the death of Hon John Lockhart, Professor Peter Schofield, a neuroscientist, Associate Professor Pamela McCombe, a clinical neurologist and Associate Professor Ian Kerridge, a clinical ethicist

<sup>66</sup> Lockhart Report at v. A similar point is expressed in the Heerey Report at 14 though not of such length

- Should the creation of human embryos for research purposes be permitted?
- Should the creation of human embryo clones by somatic cell nuclear transfer be permitted, under licence, for research, training and clinical applications?
- Should an Australian stem cell bank be established?<sup>67</sup>

In a pluralistic society, if these challenging enquiries were raised to the community without careful and meticulous thought, it is conceivable that there would be a variety of different responses which would give little to no guidance on how to proceed.

The committee considered that the:

higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prohibit the activity ... where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified ... even though some people think that an activity is unethical, it does not necessarily follow that an activity should be made illegal ... the wider the range of ethical views, the weaker it becomes the case for declaring the activity to be illegal ...<sup>68</sup>

However, it also identified that ‘there are certain moral values held in common by all communities, such as the commitment to social justice and equity and to the care of vulnerable people.’<sup>69</sup> In addition, the committee found strong community support for medical research to better understand, prevent and treat diseases.<sup>70</sup> It was of the view that:

in considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo need to be balanced against the social and moral value that other communities attach to the treatment of disease ...<sup>71</sup>

From the beginning, there was consensus among the committee members that they would not discuss the committee’s final recommendations until the advanced stage of its deliberations.<sup>72</sup> This was a suggestion raised by the late Mr Lockhart who had found this method effective in his legal profession. Members of the committee were

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<sup>67</sup> Lockhart Report at v

<sup>68</sup> Ibid at xiv

<sup>69</sup> Ibid

<sup>70</sup> Ibid at v

<sup>71</sup> Ibid at xiii

<sup>72</sup> Skene L et al, ‘The Lockhart Committee: Developing Policy through Commitment to Moral Values, Community and Democratic Processes’ (2008) *Journal of Law and Medicine* 132-138 at 133

encouraged to raise questions and articulate their views freely. They could raise devil's advocate type enquiries with unlimited opportunities to explore the various issues from differing perspectives and they need not justify their arguments. Throughout the consultative process, the members were entitled to 'change their minds without criticisms or shame.'<sup>73</sup> They should not feel compelled to maintain the same opinion as it was acknowledged and anticipated that their thoughts could 'evolve, solidify and change in response'<sup>74</sup> to the submissions, oral presentations, debates and discussions.

The chair explained a process which he called "hot-tubbing" where instead of people with diverse opinions disputing issues from preconceived notions, they should work collectively to explore what the possible solutions should be.<sup>75</sup> He further stated that they 'take off their clothes and get into a hot tub' for open and frank discussions.<sup>76</sup> The reasoning was that when people were stripped of their normal apparel, they could be comfortable with each other with less probability of faking it and also they would readily participate in the debate with the intention of seeking common ground. Thus, the "hot-tubbing" process enables an open, honest and transparent exploration of challenging issues with a higher probability of arriving at a consensus.<sup>77</sup>

It is noted that after the report was finalised, the members compared their thought processes and discovered that all of them changed their minds on certain issues during the consultative process.<sup>78</sup> They said that the "hot-tubbing"/ open discussion approach had been so effective that they were not even aware of what other members would eventually recommend until the final report was compiled.

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<sup>73</sup> Ibid

<sup>74</sup> Ibid

<sup>75</sup> Ibid. Hot-tubbing is a process used in court proceedings as a method to challenge scientific evidence

<sup>76</sup> Ibid

<sup>77</sup> The "hot-tubbing" process may seem effective in secular societies but it is unlikely to be so in other societies such as Malaysia which comprise religious communities

<sup>78</sup> Skene L et al, 'The Lockhart Committee: Developing Policy through Commitment to Moral Values, Community and Democratic Processes' (2008) *Journal of Law and Medicine* 132-138 at 133

During the consultative process, the committee in turn prompted the people who made submissions to “hot-tub”.<sup>79</sup> It explained to them that they should acknowledge the differences in viewpoints and that people from different sides of the debate should determine how to resolve such differences in the community.

It is noted that the committee consulted the Australian community extensively through a variety of means. It:

- Conducted a review website;
- Reviewed 1,035 written submissions;
- Conducted face to face meetings with key stakeholders;
- Conducted public hearings;
- Conducted private meetings at stakeholders’ request;
- Facilitated discussion forums;
- Facilitated site visits;
- Reviewed the results of focus groups and telephone survey research into public attitudes to stem cell technologies conducted by the Public Awareness Program of Biotechnology Australia;<sup>80</sup> and
- Conducted literature review of recent scientific and technological advances in human cloning, human embryo research and related matters including stem cell technologies.<sup>81</sup>

Information from these sources formed a substantial part of the report, leading to 54 recommendations. The committee sought to articulate clearly its rationale for the recommendations. The report made some recommendations that were controversial.<sup>82</sup> These included somatic cell nuclear transfer (SCNT), gametes and embryo donation and the use of fresh eggs in research. Some recommendations were non-controversial that proposed maintaining status quo in some areas.

In the following sections, the recommendations of the committee relevant to this thesis are explored, starting with the major recommendations. It is noted that two of

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<sup>79</sup> Ibid

<sup>80</sup> Lockhart Report at 82-87

<sup>81</sup> Ibid at xiii

<sup>82</sup> Ibid at xxii



the most important recommendations in the Lockhart Report were Recommendations 23 (which proposed legalising the conduct of SCNT under strict conditions) and 21 (which proposed that fresh ART embryos that are unsuitable for implantation are permitted to be used in research).

Under the recommendations discussed below, it is evident that before arriving at a recommendation, the committee took into consideration the various perspectives raised during the submissions and in forums. This is cogent evidence of the achievement of regulatory legitimacy.

## **4.10 THE MAJOR RECOMMENDATIONS**

### **4.10.1 PERMITTING THE CREATION AND USE OF HUMAN EMBRYOS CREATED BY SOMATIC CELL NUCLEAR TRANSFER IN RESEARCH (RECOMMENDATION 23)**

This was the committee's key recommendation. It was the most contentious issue and it received much attention from politicians and the general public. The committee noted that the Andrews Report recommended a three-year moratorium on SCNT rather than a permanent ban.<sup>83</sup> It also acknowledged that many submissions raised ethical concerns with the creation and destruction of human embryos for research purposes.<sup>84</sup>

The committee analysed three major objections to SCNT and dismissed all three.<sup>85</sup> The first was the slippery slope argument, that is, legalising the creation of SCNT embryos would lead to the practice of reproductive cloning.<sup>86</sup> The committee was satisfied that Australian scientists have no intention of engaging in reproductive cloning and that if that practice continued to be illegal, as reflected in Recommendation 2 that recommended that human reproductive cloning to remain banned, this prohibition would ensure that the practice would not occur. In addition, Recommendation 23 provided that the creation of embryos by SCNT be permitted

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<sup>83</sup> Ibid at 171

<sup>84</sup> Ibid at 61-67

<sup>85</sup> Ibid at 170-171

<sup>86</sup> Ibid at 170

under licence on the proviso that it would be illegal to implant the resulting embryo into the body of a woman.

The second argument was that the human clone created by SCNT is a human being.<sup>87</sup> The committee dismissed this argument because an embryo only has as much moral significance as its creators deem it to have. It agreed that an embryo clone is a human embryo and that given the conducive environment for development, it could develop into a human being.<sup>88</sup> If such an embryo was implanted into the body of a woman to achieve a pregnancy leading to the birth of a baby, this entity would have the same status as any other human embryo and enjoy the same rights and legal protection as any other human being.<sup>89</sup> However, a human embryo clone created in order to extract stem cells and not intended to be implanted, was created as a cellular extension of the original subject. The committee, therefore concluded that the moral significance of such a cloned human embryo, which was not implanted into the body of a woman, was linked closer to its potential for research developments and the development of medical treatments for serious diseases and medical conditions than to its potential as a human life.

The third argument was that embryos should not be deliberately created in order to be destroyed later for the extraction of stem cells.<sup>90</sup> This argument was dismissed because excess ART embryos are already being destroyed routinely in large numbers by allowing them to thaw from their frozen state and, therefore it would not be consistent not to accept the destruction of SCNT embryos. The committee noted that the production and destruction of such embryos is not dissimilar to the production and destruction of excess ART embryos which is widely accepted by society and legally permitted and thus, to permit one but not the other is not consistent. In addition, to allow the former but not the latter, appeared to place more importance to the infertility treatment than the medical treatment of serious illnesses and conditions. In view of the broad scope of diseases and conditions that could be treated as a result of this activity, the committee concluded that research using cloned human embryos should be legally allowed.

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<sup>87</sup> Lockhart Report at 170

<sup>88</sup> See Chapter 2.6 of this thesis

<sup>89</sup> However, there is no such evidence; see Chapter 2.6 of this thesis

<sup>90</sup> Lockhart Report at 170

The committee heard that further development in this area of research requires the creation of human embryo clones to generate embryonic stem cells that are patient-matched for development of specific cellular therapies.<sup>91</sup> The committee noted that embryonic stem cells have potentially useful applications in other areas of medical research, for instance, studying cell differentiation in healthy as well as diseased tissues and disease modelling studies.<sup>92</sup> Such studies could increase understanding of disease processes and lead to cures for diseases. As provided by the Stem Cell Science Ltd:

.... that could be used to better understand in the laboratory the progression of complex diseases such as diabetes, motor neuron disease, Huntington's and Parkinson's diseases.<sup>93</sup>

Some submissions argued the usefulness of SCNT for drug screening. Stem Cell Sciences Ltd said, '... SCNT could prove of great value to the pharmaceutical industry in initial stage screening of new drug candidate ... also the discovery of better medicines that can reach the clinic sooner'.<sup>94</sup> The committee's view was that there is scientific merit in the use of embryonic stem cells for this type of research.

The committee acknowledged the progress that has been made in adult stem cell research so far and this type of stem cells has already been used successfully in the treatment of certain diseases like bone marrow transplantation.<sup>95</sup> However, the committee also noted that the potentiality of adult stem cells, in terms of the number of cell types that could be generated, was still unclear and certainly less compared to HESC as of the present day.<sup>96</sup>

Professor Julian Savelescu argued that a preferred ethical starting point would be to ask why HESC research is not supported and he stressed that this research should be legally permitted to proceed because of its potential to save lives and that with

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<sup>91</sup> Lockhart Report at 61

<sup>92</sup> Ibid at 62

<sup>93</sup> Ibid

<sup>94</sup> Ibid

<sup>95</sup> Ibid at 170

<sup>96</sup> Ibid. See Chapter 2.5.1 which explores adult stem cell and its benefits

delays in the conduct of this research, ‘we may be responsible for the premature deaths of many people.’<sup>97</sup>

The committee carefully considered all submissions on HESC and adult stem cells and noted the following.<sup>98</sup> First, a number of the arguments on the clinical utility of embryonic and adult stem cell research were based on speculation rather than on established data. Secondly, while the findings of HESC research had not yet translated into any clinical trials or medical treatments at the time, the use of excess ART embryos to derive HESC lines has contributed to progress in advancing the understanding of stem cells and research directed to future therapeutic outcomes of stem cell research. Thirdly, while there has been progress in adult stem cell research, the developments in this type of research did not remove the necessity to make progress in HESC research and the committee agreed with the strong opinion of a number of researchers who are of the view that both types of research should be permitted to proceed simultaneously. Fourthly, because of the broad range of human diseases and conditions that may be treated by therapies developed from stem cell research, the number of patients who may ultimately benefit from such research was high.

The committee heard that SCNT research was being conducted in countries where the SCNT research was legally permitted or where there were no regulations in place.<sup>99</sup> Therefore, many respondents argued that prohibition of SCNT should be lifted in Australia to allow its researchers to continue to contribute to the biotechnological developments in the field.<sup>100</sup> Some respondents submitted that by continuing the prohibition on SCNT, Australian researchers would be at a disadvantage in terms of the exploration of innovative medical treatments that might lead to serious consequences for Australian research and the availability of new therapies.<sup>101</sup>

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<sup>97</sup> Professor Savelescu is the director of Oxford Uehiro Centre for Practical Ethics, University of Oxford. Lockhart Report at 63

<sup>98</sup> Ibid at 166

<sup>99</sup> Ibid at 170

<sup>100</sup> Ibid at 137-138

<sup>101</sup> Ibid at 63

A number of respondents argued that if SCNT research is legally permitted, every research project should be evaluated adopting a strict regulatory framework like the statutory licensing system for research on excess ART embryos. Dr Stephen Junk explained:

controlled ethically approved SCNT research should be approved to appropriately licensed institutions to ascertain whether this form of technology may prove beneficial in the future. Without the research, we will never know.<sup>102</sup>

Based on the evidence of experts who worked directly in one or both fields of stem cell research, adult or embryonic, the committee supported the need for further research involving both types of stem cells to improve knowledge and to develop effective disease treatments. The committee concluded that creation of human embryos by SCNT should be allowed under licence, according to strict regulatory guidelines which should incorporate strict guidelines for egg donation. The reasons are summarised as follows:<sup>103</sup>

- While the intention of human reproductive cloning activity is to clone a human being, the objective of SCNT is to copy a person's cells and provided the patient provides consent, there are no serious ethical issues;
- Compared to the creation of a human embryo by normal sperm/egg fertilisation, an embryo created by SCNT technology does not amount to the creation of a potential new individual because it is not intended to be implanted into the body of a woman;
- While an SCNT embryo is not distinguishable from other types of human embryos, it is created deliberately and specifically for research purposes only and it is not intended to be implanted;
- The deliberate creation and subsequent destruction of such an embryo is not different to the deliberate creation and subsequent destruction of excess ART embryos which is widely accepted by society and legally permitted; and
- To permit SCNT would not amount to a substantial progress to the next level.

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<sup>102</sup> Lockhart Report at 65  
<sup>103</sup> Ibid at 171

In view of these reasons, the committee suggested that SCNT be permitted under licence as reflected in Recommendation 23 which provided that ‘human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.’ This recommendation amounted to progressing to the next level, from permitting the use of ART embryos in 2002 to permitting SCNT. However, this controversial activity is permitted as long as the activity satisfies all the criteria outlined in the amended Act and the embryos are not implanted into the body of a woman or allowed to develop for more than 14 days. Such stringent requirements should allay the concerns of the general public. Permitting SCNT research is the most contentious recommendation in the Lockhart Report and it is evident from the discussion above that before arriving at this recommendation, the committee took into account the various perspectives raised.

#### **4.10.2 EGG, SPERM AND EMBRYO DONATION (RECOMMENDATIONS 31-33)**

The principles of consent for participants in medical research are found in the NHMRC’s *National Statement* and the *ART guidelines*. They were developed by AHEC, a principal committee of NHMRC to guide ethical research participation. At the time of the Lockhart Report, the 1999 National Statement provided uniform national guidelines for ethical conduct of research including humans (this was replaced by the 2007 version). The *National Statement 1999*<sup>104</sup> set out the overall ethical principles for research involving humans and human tissues. The committee dealt with the *ART Guidelines 2004*,<sup>105</sup> which included specific requirements for research involving gametes and embryos. Collectively, these guidelines emphasised that it is unethical to coerce potential research participants in any way. Accordingly, the committee put forward Recommendation 31 which provided that the current principles of consent for participation in medical research must apply to sperm, egg and embryo donors to ensure that decisions are freely made.

<sup>104</sup> The *National Statement 1999* was updated in 2007 subsequent to the *Amendment Act 2006*

<sup>105</sup> The *ART Guidelines 2004* was also updated in 2007 subsequent to the *Amendment Act 2006*

Some serious ethical concerns were put to the committee concerning egg donation for SCNT. The committee noted the following concerns:

- The real and potential health risks to egg donors, short and long term;
- The possibility of coercion of vulnerable people, for instance, research assistants and related donors;
- That women undergoing ART treatment programme may be requested, that is indirectly coerced, to donate their eggs for research; and
- That donors receive no direct medical benefit from the research.<sup>106</sup>

In the light of these concerns, the committee's view was that, as reflected in Recommendation 32 which provided that 'the NHMRC should develop guidelines for egg donation'. With these firm guidelines, they ensure that the egg donors have all the appropriate information to give free consent.

During the review, a question was raised as to whether female donors could be paid for their eggs.<sup>107</sup> The committee heard argument in favour of the continuation of prohibition of payment for human embryos and gametes.<sup>108</sup> There were also arguments made in favour of reimbursing the donors for out-of-pocket reasonable expenses, for instance, expenses incurred which are related to the egg donation such as transport costs and loss of wages. To avoid commodification of body tissues and to limit the risk of exploitation of women, the committee formed the view that the payment should not be permitted, beyond the reimbursement of reasonable expenses. This was reflected in Recommendation 33 which provided that 'the present prohibition of the sale of sperm, eggs and embryos but that the reimbursement of reasonable expenses should continue to be permitted'.

Recommendations 31 and 32 protect the interests of women and aimed at allaying concerns about exploitation of women in SCNT research. Reimbursing female donors for out-of-pocket reasonable expenses under Recommendation 33 is reasonable. It may also be argued that women should also be paid for their eggs in view of the discomfort and various health risks associated with egg donation.

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<sup>106</sup> Lockhart Report at 65

<sup>107</sup> Ibid at 121 and 133-135

<sup>108</sup> Ibid

Compared to blood donation, egg donation is more invasive. Women have to take drugs for stimulating ovulation and the eggs must be removed surgically. Given the invasiveness of egg extractions and health risks,<sup>109</sup> it would be reasonable that these donors are compensated.<sup>110</sup> New York was the first American state to permit scientists to use public research funds to pay women donating their eggs for use in research.<sup>111</sup> It has been argued:

prohibiting them from being paid may seem an unwarranted restriction of their autonomy- the hand of the nanny state. We allow people to work in risky jobs and to be paid for doing so: film stunts, bridge constructions - even prostitutions. The state protects workers' safety as much as possible but it does not discourage them by prohibiting payment. Indeed, women who donate eggs for research may be better protected by allowing payment with open procedures and proper regulation than by prohibiting payment.<sup>112</sup>

#### **4.10.3 PERMITTING THE USE OF ANIMAL EGGS (RECOMMENDATION 24)**

The committee noted the problem of shortage of human eggs and considered whether alternative sources, such as eggs from animal sources, should be permitted.

This approach is not acceptable to some. Mrs Nola Drum said:

I am very fearful that scientists will begin to see chimeras as very realistic alternative to the problem of finding enough eggs to conduct their research.<sup>113</sup>

Despite the controversial nature of this issue, it was not discussed in great detail in the Lockhart Report.<sup>114</sup> Even so, the committee recommended the use of animal eggs as a substitute for human eggs. Recommendation 24 stated that 'in order to reduce the need for human oocytes [eggs], transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.' This stresses that

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<sup>109</sup> Check E, 'Ethicists and Biologists Ponder the Price of Eggs' (2006) *Nature* <http://www.nature.com/nature/journal/v442/n7103/full/442606a.html> (10 August 2006)

<sup>110</sup> Ibid. For more information on health risks and inconvenience suffered by the female donors, see the argument on exploitation of women in this chapter

<sup>111</sup> 'New York State to Pay Women for Egg Donation' (2009) <http://www.cellmedicine.com/new-york-state.asp> (26 June 2010)

<sup>112</sup> Skene L, 'Donating Eggs for Research is Tough—so Why not Pay for it?' (18 June 2010)

<sup>113</sup> Lockhart Report at 67

<sup>114</sup> Ibid at 66-67



permitting the use of animal eggs on the proviso that the activity satisfies all the criteria outlined in the amended legislation is important as it ensures that reproductive cloning does not occur.

#### **4.10.4 USE OF FRESH EGGS (RECOMMENDATIONS 20-22)**

These three recommendations concern the use of fresh ART embryos for research as opposed to the use of frozen embryos. This type of embryo is unsuitable for implantation as it is unfit. Some of these embryos are identified as carrying a genetic disease following preimplantation genetic diagnosis (PGD).

The committee received submissions about advantages of using fresh embryos rather than frozen embryos for research, training and quality assurance activities.<sup>115</sup> However, the use of fresh embryos was precluded by the requirements under the Act because an embryo must first be declared as an excess embryo and then proper consent procedures must be complied with. Proper consent involves a two-week cooling-off period, during which time responsible persons could withdraw their consent. Under such arrangements, embryos that are not suitable for implantation for any reason, including the ones that are found to carry a genetic disease diagnosed by PGD technology, are allowed to succumb and are therefore unavailable for research. ART researchers and practitioners informed the Committee that such embryos would be a useful source of fresh embryos for research, training and quality assurance activities. Also HESC researchers intended to generate stem cells from these embryos carrying genetic diseases after PGD in order to study the cause and treatment of the genetic disease suffered by the diagnosed embryo.<sup>116</sup>

The committee noted that the *RIHE Act 2002* was equivocal as to whether PGD embryos could be considered to be excess ART embryos. It was not clear whether they were not suitable for reproductive use in the first place and also whether they could ever be used for research purposes because they would have to be first frozen under the terms of the *RIHE Act*.<sup>117</sup> The ‘cooling off’ period also precluded their

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<sup>115</sup> Ibid at 168

<sup>116</sup> Ibid

<sup>117</sup> Ibid at 169

use as fresh embryos. The committee considered that within the legislation and licensing arrangements, there had to be clear and unambiguous provisions for declaring such PGD embryos which were unsuitable for implantation, as ‘excess embryos.’ The committee was of the view that these embryos should be legally permitted for use in research, training and improvements in clinical practice.<sup>118</sup>

The committee acknowledged that, in some cases the suitability for implantation is an objective decision, for instance, when the embryo has been diagnosed by PGD to carry a genetic disorder. In other cases, it may more of a subjective decision, in the diagnosis, for instance, when the embryo appears to be ‘less healthy’.<sup>119</sup> Therefore, the committee concluded that, as reflected in Recommendation 20, which provided that ‘an expert body should formulate objective criteria to define those embryos that are unsuitable for implantation,’ such criteria could include embryos that have not undergone cell divisions, carry additional pronuclei or show major chromosomal defects.

The committee also recommended that these fresh embryos, unsuitable for implantation, as defined by the objective criteria, should be permitted for use under licence for research, training and improvements in clinical practice. Recommendation 21 provided that ‘fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence for research, training and improvements in clinical practice.’ Recommendation 22 provided that ‘fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used under licence for research, training and improvement in clinical practice.’

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<sup>118</sup> Ibid at 169

<sup>119</sup> Ibid

#### 4.10.5 CONSENT ARRANGEMENTS FOR THE DONATION OF EMBRYOS (RECOMMENDATIONS 29-30)

New areas of research were generating situations that might not have been fully envisaged when the *ART guidelines* were developed.<sup>120</sup> The committee therefore recommended that the NHMRC should review certain aspects of the *ART guidelines*. These aspects are reflected in Recommendation 29 on each of four scenarios. The Recommendation provided that ‘the NHMRC should review its guidelines in relation to consent to research on excess ART embryos in order to clarify the consent process, in relation to the following:

- (i) donors of excess ART embryos may be able to choose not to be contacted at some later stage to give consent to a particular research proposal;
- (ii) the human research ethics committee (HREC) can determine that the researcher need not ask for further consent to use embryos already declared ‘excess’;
- (iii) the development of an appropriate consent form that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess; and
- (iv) the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used once the embryo is declared excess.’

Donors of excess ART embryos expressed concerns about the second stage of the consent process for the donation of excess ART embryos, where they were asked for their consent for a specific research project.<sup>121</sup> They claimed that this stage is particularly stressful. They stated they are approached by researchers for consent to a specific research project at a future date, possibly many years later, after the initial agreement to donate the embryo for research. This revives the emotional issue of the fate of the embryo. As IVF Australia submitted:

We are reticent to seek second date approval from couples where an extended time period has elapsed. Whereas some couples may appreciate the contact, we believe many couples would view it is an unnecessary invasion of their lives, possibly resurrecting past disappointments and heartaches.<sup>122</sup>

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<sup>120</sup> The committee acknowledged the efforts in the development of the *National Statement 1999* and the *ART Guidelines 2004*, *ibid* at 115

<sup>121</sup> Lockhart Report at 117-118

<sup>122</sup> *Ibid* at 118

The committee noted that there are different purposes/ intent of research that were not known until the embryos are selected for a specific project.<sup>123</sup> It acknowledged that there are also people who wish to be involved in the decision about the particular type of research for which their embryo is used. Therefore, the committee's view was that the AHEC should review the *ART guidelines* for consent and, in particular, the arrangements that could be developed to exclude further contact at a later stage for people who preferred this option.<sup>124</sup> The AHEC review should take into account the preference of the embryo and gamete donor and the HREC should be involved to determine whether this was possible.

The committee also noted that there is a significant difference between research with human embryos for the purposes of improving ART services (where there is no ongoing live biological material produced from the embryos) and research with human embryos for the purpose of creating HESC lines (which are immortal and will be used in ongoing research.) The committee therefore considered that it is necessary for consent to be obtained as it is important for people to be fully informed about the commercial potential of their donation.<sup>125</sup> In addition, the committee recommended that appropriate conditions be put in place for personal use of any products of the research by the donors, such as for the treatment of children who are matched with any stem cell lines derived.<sup>126</sup>

The arrangements for consent provide for the use of excess embryos in frozen storage, but not for the use of embryos that are unsuitable for implantation, that is, unfit embryos (including PGD embryos). This category of unfit embryos will never be used for reproductive purposes and would normally be discarded. There were views expressed on the appropriate consent arrangements for this category of embryos. One view was that 'there should be no need to wait for the embryo to be declared excess and then wait for the 14 days cooling off period.'<sup>127</sup> A similar opinion was expressed by Professor Agnes Bankier of Genetic Health Service Victoria; she said that in PGD, all couples must go through counselling first and

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<sup>123</sup> Ibid at 174

<sup>124</sup> Ibid

<sup>125</sup> Ibid at 175

<sup>126</sup> Ibid

<sup>127</sup> This was the view of Professor John Morgan, director of the Australian Institute of Ethics and the Professions at 120 of Lockhart Report

discuss the fate of their embryos.<sup>128</sup> She said that potential parents would not go through PGD unless they wish to avoid having a baby carrying the genetic disease, and so consent obtained before the PGD procedure would not need the cooling-off period. The committee considered that AHEC should develop guidelines for consent to facilitate the use of embryos unsuitable for implantation as reflected in Recommendation 30 which provides that ‘the NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvement in clinical practice.’

## **4.11 NON-CONTROVERSIAL RECOMMENDATIONS**

This section explores several non-controversial recommendations in the Lockhart report which are important to this thesis. As for the licensing arrangements (Recommendations 34-37) and monitoring powers of the Licensing Committee (Recommendations 38-39), these are considered in a separate chapter in Chapter 6 of this thesis as these involve lengthy discussions and critique.

### **4.11.1 THE CONTINUITY OF NATIONAL LEGISLATION (RECOMMENDATION 1)**

The committee acknowledged that in multicultural Australia, disagreements remain on the ethics of research involving embryos. However, on the whole, both proponents and opponents of the research agreed that the present system of legislation was valuable.<sup>129</sup> It is interesting that opponents to the research believe that regulation and supervision of such research is preferable to no restrictions. Proponents conceded that the present system provide a means where the research is supervised and given approval to proceed. The committee concluded that Australia should continue to have national legislation imposing prohibitions on human reproductive cloning as well as imposing strict control and monitoring under licence of human embryo research as reflected in Recommendation 1<sup>130</sup> which provided that ‘clinical practice and scientific research involving assisted reproductive

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<sup>128</sup> Lockhart Report at 120

<sup>129</sup> Ibid at 182

<sup>130</sup> Given that legislation on research involving embryos is effective in Australia, this thesis takes the view that Malaysia too should enact legislation on this area, the main argument of this thesis

technology (ART) and the creation and use of the human embryos for research purposes should continue to be subject to specific national legislation.’

#### **4.11.2 THE CONTINUITY OF THE BAN ON HUMAN REPRODUCTIVE CLONING (RECOMMENDATION 2)**

Most respondents supported the continuation of legislation to maintain the prohibitions of human reproductive cloning and other reproductive practices considered unacceptable or unsafe.<sup>131</sup> This view was held primarily on the basis of ethical and safety concerns. The committee heard strong agreement among all groups that human reproductive cloning should continue to be prohibited on ethical grounds which include social and psychological implications of creating genetic copies of other living or dead individuals and concerns about eugenic-style selection of individuals with particular genetic characteristics. As the Industrial and Social Research Associate Pty Ltd said:

... cloning would be a poor method indeed for improving on the human species. If widely adopted, it would have a devastating impact on the diversity of the human gene pool.<sup>132</sup>

Serious health and safety issues associated with the birth of live, cloned animals are seen as reasons to prohibit this procedure in human beings.<sup>133</sup> Stem Cell Science Ltd said:

... the consistently high rate of miscarriage, premature birth and developmental deficiencies in animal cloning studies dictate the inherently unsafe nature of cloning technology for the purposes of reproduction.<sup>134</sup>

Dr Kevin Ward explained that the abnormalities include large birth weights, feeding problems, endocrine and immunological deficiencies and suspected abnormalities of behaviour.<sup>135</sup> In his opinion, they are associated with abnormal development ‘due to imprecise reprogramming of the genome of the initial nuclear transfer-derived zygote.’

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<sup>131</sup> Lockhart Report at 60

<sup>132</sup> Ibid

<sup>133</sup> There are numerous instances of failures of animal cloning. Dolly developed arthritis and was euthanised at eight years old because of a degenerative lung condition

<sup>134</sup> Lockhart Report at 60

<sup>135</sup> Ibid

However, a minority group disagreed that human reproductive cloning be banned.

Mr Malcolm Lamberts argued:

because we accept identical twins, we should also accept cloned humans and the only difference is that the person and their identical sibling would be born years apart rather than minutes apart.<sup>136</sup>

The committee concluded that, on balance, human reproductive cloning should be prohibited because of the two reasons outlined above, that is ethical and safety concerns. Recommendation 2 therefore provided that reproductive cloning should continue to be prohibited. This Recommendation reflects the view of majority of Australians and prevailing attitudes worldwide.

#### **4.11.3 AMENDMENT TO DEFINITION OF HUMAN EMBRYO (RECOMMENDATION 28)**

Recommendation 28 provided that the definition of a ‘human embryo’ in both Acts should be changed to:

A human embryo is a discrete living entity that has a human genome or an altered human genome that has arisen either from:

- (i) the first mitotic cell division when fertilisation of a human egg by a human sperm or
- (ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has potential to develop up to, or beyond, 14 days and has not yet reached eight weeks of development.

The second part of the definition clarified that an entity which is produced by any other process, that is, without fertilisation by a sperm, should still qualify as an embryo, with the same biological potentiality. The committee explained that the general community’s understanding of a human embryo is very broad, that is, from the moment of conception to the time it develops into a foetus at eight weeks after conception.<sup>137</sup> While there has been no disagreement about the latter boundary, that is, eight weeks after conception, the earlier boundary is more difficult to pinpoint. The committee referred to the Licensing Committee (LC)’s discussion paper (DP)

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<sup>136</sup> Ibid

<sup>137</sup> Ibid at 98

on the definition of an embryo.<sup>138</sup> The DP described emerging technologies including SCNT and advised that the most appropriate marker for defining the potential for continuing development may be the appearance of the primitive streak because it is at this stage that the multi-cellular entity that forms the new individual first appears.<sup>139</sup> The significance of the proposed change is that it adopted a definition of an embryo at a slightly later stage of development, which enables much valuable research including SCNT to occur. Accordingly, the Report proffered forward Recommendation 28.

#### **4.11.4 EXCESS ART EMBRYOS SHOULD CONTINUE TO BE AVAILABLE FOR RESEARCH (RECOMMENDATION 14)**

The committee considered that overall there is support for the use of excess ART embryos for destructive research, for ART research as well as to obtain HESC. This view was expressed by scientists, organisations, individuals<sup>140</sup> and a number of ART consumers who have donated their excess embryos for research.<sup>141</sup> During the review, there were many submissions where couples expressed their preference for their embryos to be used for research than wasted.<sup>142</sup> However, other respondents disagreed and argued that all uses of human embryos should be not be permitted.<sup>143</sup>

The committee noted that the use of excess ART embryos in research to derive HESCs had contributed to the progress in understanding stem cells and research directed to therapeutic outcome of the research.<sup>144</sup> In addition, it also noted that the continuous developments and progress in adult stem cell research do not remove the necessity of conducting HESC research altogether. The committee agreed with the view of many researchers that both types of research should be allowed to proceed. It was of the view that a broad range of diseases and conditions may be treated by therapies developed from stem cell research and, therefore many patients might benefit from such research.<sup>145</sup> Accordingly, Recommendation 14 stated that ‘the use

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<sup>138</sup> Ibid at 93, see Chapter 2.6 of this thesis

<sup>139</sup> See Chapter 2.6 of this thesis

<sup>140</sup> Lockhart Report at 77

<sup>141</sup> Ibid at 166

<sup>142</sup> Ibid at 78

<sup>143</sup> Ibid at 77-78

<sup>144</sup> Ibid at 166

<sup>145</sup> Ibid at 166



of excess ART embryos in research should continue to be permitted, under licence, as under current legislation’ as they are going to be destroyed anyway.

#### **4.11.5 TRADE AND INTERNATIONAL EXCHANGE OF HUMAN REPRODUCTIVE MATERIALS AND STEM CELLS (RECOMMENDATIONS 42-43)**

Recommendations 42 and 43 concern the trade and international exchange of stem cells and other human reproductive materials such as gametes and embryos. Some researchers noted the importance of Australian researchers getting access to further cell lines from overseas.<sup>146</sup> But they expressed the concern on whether the imported cell lines derived overseas followed practices which were consistent with Australian legislation.<sup>147</sup> Recommendation 42 provided that ‘the import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority’ but it did not include detailed information about how this was implemented.

The committee heard from some researchers that the arrangements had not affected their research.<sup>148</sup> The committee expressed the view that requirements for the import and export of human biological material were satisfactory for ethically derived human embryonic stem cells.<sup>149</sup> Accordingly, Recommendation 43, provided that ‘the existing requirements for the import and export of human biological materials are satisfactory and for ethically derived human embryo stem cells, no further restrictions are necessary.’

#### **4.11.6 BIOTECHNOLOGY AND COMMERCIALISATION (RECOMMENDATIONS 44-46)**

During the review, strong views were expressed that sperm, egg and embryos should not be commodified by permitting people to sell their own gametes and embryos.<sup>150</sup> Many respondents expressed their wish in seeing altruistic donations translate into public benefit as well as therapeutic applications arising from the

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<sup>146</sup> Ibid at 131

<sup>147</sup> Ibid at 132

<sup>148</sup> Ibid at 179

<sup>149</sup> Ibid at 180

<sup>150</sup> Ibid at 133-134

research. As reflected in Recommendation 44, ‘trade in human gamete [human egg and sperm] or embryos or any commodification of these items, should continue to be prohibited’, that is, these biological materials cannot be bought or sold.

The committee heard that commercialisation of research was based on the premise the gametes and embryos were donated altruistically. This premise avoids the commodification of body tissues at the stage of donation, though commercial benefits may emerge over time.<sup>151</sup> Concerns were expressed that benefits and profits should be in the public domain and therapies should be available within the public health system. Therefore, Recommendation 45 provided that ‘donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by research ethics committee about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.’ This is to ensure that donors of tissues should be informed that while there is potential for commercial gain in the use of their stem cell line, they do not share the financial gain.

In contrast to the concerns expressed about the commodification of gametes and embryos, the committee also noted that stem cell technology was a useful platform for investment by the biotechnology industry and products with commercial potential could be developed from altruistic donations.<sup>152</sup> Accordingly, it provided that investment was necessary to develop potential therapies which would require the research and development activities to be commercialised. The committee was therefore of the view, that commercialisation was an essential aspect of research. Without investment, it would not be possible to develop new therapeutic products.<sup>153</sup> Recommendation 46 therefore provided that ‘the development of biotechnology and pharmaceutical products rising from stem cell research should be supported.’

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<sup>151</sup> Ibid at 140

<sup>152</sup> Ibid at 141

<sup>153</sup> Ibid

#### **4.11.7 THE ESTABLISHMENT OF A NATIONAL STEM CELL BANK AND NATIONAL REGISTER FOR EXCESS ART EMBRYOS (RECOMMENDATIONS 47-49)**

The committee noted that advantages had been identified for the establishment of an Australian national stem cell bank. These included benefits to research, benefits to researchers and quality control.<sup>154</sup> The committee considered that stem cell banks facilitate research by making stem cell lines more widely available to the international research community and a stem cell bank ensured that minimum numbers of embryos are used under strict conditions.<sup>155</sup> The committee heard overall strong support for an Australian national stem cell bank in order to provide improved access to stem cell lines for research and to provide a quality control mechanism for stem cell research.<sup>156</sup> Some submissions expressed conditional support for stem cell bank, provided that it excluded the deposit of HESC.<sup>157</sup> Recommendation 47 concluded that ‘a national stem cell bank should be established’ as the bank would make stem cells, embryonic and adult stem cells, more widely available to researchers and limit the number of embryos required for derivation of stem cell lines.

The committee considered the Australian Stem Cell Centre (ASCC) could administer the national stem cell bank, given it already had a stem cell banking facility.<sup>158</sup> Recommendation 48 provided that ‘consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.’ However, the committee did not suggest how an Australian stem cell bank is managed or regulated other than recommending that it is administered by the ASCC.

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<sup>154</sup> Ibid at 146-147

<sup>155</sup> Ibid. At the Sydney consultation, Dr Kuldip Sidhu said that, while there were 225 stem cell lines around the world, international quality control was difficult because ‘researchers do not know the cell type, karyotype or quality of most cell lines.’ His view was that until the quality of international stem cell line is guaranteed, Australia should adopt its own quality control system; *ibid* at 147

<sup>156</sup> *Ibid* at 145

<sup>157</sup> Submission by the Christian Democratic Party (Western Australian Branch) at 146 of Lockhart Report

<sup>158</sup> Lockhart Report at 181

As there are many excess ART embryos donated, it was proposed that a register of excess ART embryos be established to ensure the most efficient use of such a valuable resource. Many respondents were concerned that there might be no opportunity for the embryos to be used in research projects. The committee considered the establishment of a national register of donated embryos that should be maintained by the Licensing Committee.<sup>159</sup> The committee stated that this register would serve the function of facilitating embryo donation for research and provide a transparent account of the number of donated excess ART embryos. So, Recommendation 49 provided that ‘a national register of donated excess ART embryos should be established.’ It recommended that these new approaches would only be permitted in the context of a strict prohibition on cloning for reproduction.

#### **4.11.8 BINDING RULING ON INTERPRETATION OF THE ACT BY LICENSING COMMITTEE (RECOMMENDATIONS 50-52)**

While both proponents and opponents of human embryo research preferred to have legislation rather than no regulation, a number of concerns were expressed about the capacity of legislation to respond to research in a rapid-developing area of technology. The concerns included difficulties in foreseeing advances in knowledge and potential new uses of the technology, ambiguities leading to difficulties in interpretation of legislation and unfair exposure of researchers to potential prosecution.<sup>160</sup> Recommendation 50 provided that ‘the Licensing Committee should be authorised under the *PHC Act 2002* to give binding rulings on the interpretation of the Act or regulations made under the Act, on condition that it reports immediately and in detail to the NHMRC and to Parliament on such rulings.’

In the face of rapidly changing technology, these rulings could reduce the need for ongoing review of the Acts. So, Recommendation 51 provided also that ‘the Licensing Committee should be authorised by *RIHE Act 2002* to give binding rulings and to grant licence on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but it is within their tenor, on condition that the Licensing Committee reports immediately and in detail to the NHMRC and to Parliament on any rulings it gives or any

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<sup>159</sup> Ibid

<sup>160</sup> Ibid at 153-154

licences it grants, in that way.’ In summary, these Recommendations provide that the Licensing Committee should be given powers to provide rulings on the interpretation of practices that are currently prohibited under the Acts so long as it reports details of them to both NHMRC and Parliament.<sup>161</sup>

In addition, the Licensing Committee should have the power to grant licenses for research that is not expressly permitted in the *RIHE Act* but is within the tenor and purposes of the Acts. If the LC were to issue such a licence, it should be required to report immediately to both NHMRC and to Parliament. This additional power would, it is submitted, assist regulators to attain regulatory connection. This is the third challenge in regulating new technologies. However, it is acknowledged that these Recommendations raise significant constitutional issues relating to the exercise of judicial power by a non-judicial body as found in *Brandy v Human Rights and Equal Opportunity Commission* (1995).<sup>162</sup>

It is also important that researchers, who act on the basis of these proposed LC rulings, should have statutory immunity from prosecution to ensure protection for those people who act in good faith on such advice. Recommendation 52 provided that ‘a researcher who conducts research on the basis of a ruling or a licence should be protected from liability, provided that they act in accordance with the relevant ruling or licence.’ This recommendation provided an insurance against there being unexpected breakthroughs in technology. The committee noted that there are precedents for this approach in other areas of law. For instance, in taxation, the Commissioner for Taxation can issue rulings on the applicability and interpretation of taxation legislation.<sup>163</sup> Such an approach complements the monitoring and compliance procedures that would assist researchers to comply with the law, with prosecution an action of last resort.

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<sup>161</sup> The *RIHE Act 2002* appears to give the Licensing Committee powers under both Acts but according to Lockhart report, it would be preferable for the powers to be specifically conferred under the Act. See Lockhart Report at 155

<sup>162</sup> 127 ALR 1

<sup>163</sup> Lockhart Report at 182

#### **4.11.9 FURTHER REVIEW OF THE ACT (RECOMMENDATION 53)**

A provision in the legislation provides for a mandatory review of the legislation within a reasonable time frame. This review is crucial to ensure and maintain regulatory connection. The Lockhart Report recognised developments in the science were always before recommendations were proposed to reform the law. Recommendation 53 provided that ‘in view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.’

#### **4.11.10 PUBLIC EDUCATION (RECOMMENDATION 54)**

The committee noted that in Australia, public knowledge of stem cell research was limited and it also noted the frequent overestimation of the likely time frames for the translation of research into therapeutic outcomes by the public and the scientific community.<sup>164</sup> The committee therefore recommended that accurate presentations and reporting of research advances are critical for public engagement, including an emphasis on realistic assessments of benefits, both short-term and long-term, of the research. This is reflected in Recommendation 54 which provided that ‘there should be public education and consultation programs in the area of science that are relevant to the Acts.’ The committee noted the need for further public education and consultation programmes to enable engagements and understanding of these fields of research as well as their application and the NHMCR, through the Licensing Committee, could play an important role.<sup>165</sup> This is an important recommendation because well informed members of the public can actively engage debate and this ensures regulatory legitimacy.

#### **4.12 CONCLUSION**

Regulatory legitimacy, in Brownsword’s terms, refers to a regulatory position considered by the constituencies in a society as acceptably legitimate and ethically appropriate. This chapter illustrates an important and striking feature of the Australian regulatory framework, that is, there were extensive public consultations conducted prior to the enactment of legislation/ amending legislation and issuing

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<sup>164</sup> Lockhart Report at 183  
<sup>165</sup> Ibid

fresh guidelines/ revision of existing guidelines. Australia is a secular society, consisting of different religious and moral values. In addition, there were formal and structured debates in Parliament where controversial issues are fully argued.

The conduct of such public consultations and parliamentary debates. ensure not only regulatory legitimacy and as Brownsword argues, the more consensus regulators can gather from regulatees, the more likely they will achieve regulatory effectiveness, the second regulatory challenge.<sup>166</sup>

While there was no public consultation held in the preparation of the AHEC Report, a draft of the report was circulated to a broad range of persons knowledgeable in the field, including scientists and ethicists, for their feedback. In 2001, prior to the release of the Andrews Report, which led to the enactment of *PHC Act 2002* and *RIHE Act 2002*, there were two public consultations conducted as the committee intended to involve the public at large to explain and explore the range of views. In addition, the committee collected written submissions and exhibits.

In 2005, prior to the release of the Lockhart Report, which led to the *Amendment Act 2006*, the review Committee held extensive consultations that involved a cross section of the Australian society with successful attempts to balance the diverse views of the society, applying the 'hot-tub' process. The broad range of consultations conducted included facilitating forums, conducting public hearings and private meetings, conducting a review website, reviewing written submissions, holding meetings with stakeholders, facilitating site visits, reviewing results of focus groups and telephone survey research into public attitudes to stem cell technologies and conducting literature review of latest scientific and technological advances in human cloning, human embryo research and related matters including stem cell technologies. Data collected from these sources have led to the recommendations in the Report. In the imminent legislation review to be held later this year (2010), it remains to be seen whether consultations of similar scales will be conducted and it is probable that they are likely to be. With these strategies to

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<sup>166</sup> See Chapter 3.2.2 of this thesis

conduct public consultations as well as Parliamentary debates, it is evident that the Australian regulatory regime on stem cell research achieves regulatory legitimacy.

Following the review, the Lockhart committee handed its findings to the Australian Government. The developments post-release of the report and Parliamentary debates are explained in the next chapter of this thesis. The focus of the chapter is to determine the extent to which the Australian regulatory regime on cloning and stem cell research maintains Brownsword's regulatory connection.



## **5: MAINTAINING REGULATORY CONNECTION: BEYOND LOCKHART REVIEW**

### **5.1 INTRODUCTION**

This chapter explores whether the Australian regulatory framework on cloning and stem cell technology is responsive and evolves with the changing times and thus maintains regulatory connection.<sup>1</sup> With reference to Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research report (2001) (Andrews Report), it provided that ‘the regulatory framework must be transparent, accountable and responsive.’<sup>2</sup>

The previous, this and the next chapters also assess the effect of statutory provisions requiring, found in both Acts, mandatory review of the legislation to be conducted within a reasonable time frame. This chapter also explores the rapid implementation of the recommendations in the Lockhart Report by the enactment of amending legislation which was accompanied by revisions to the *National Statement on Ethical Conduct in Research involving Humans 1999* (*National Statement 1999*) and *Ethical Guidelines on Assisted Reproductive Technology 2004* (*ART Guidelines 2004*) to reflect the amendments made in the Acts. These periodic mandatory reviews of the legislation leading to amendments made to legislation as well as guidelines and the creation of new guidelines ensure regulatory connection with the fast changing scientific developments.

### **5.2 POST LOCKHART: THE AUSTRALIAN GOVERNMENT’S RESPONSE TO THE LOCKHART REPORT**

Initial indications from the Government suggested rejection of the recommendations in the Lockhart Report. On 31<sup>st</sup> August 2006 a report, released by the Department of the Prime Minister and the Cabinet concluded that there had been no significant developments in the science to support amendment to the legislation.

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<sup>1</sup> The previous chapter explained the earlier developments of the Australian regulatory framework on cloning and stem cell technology from the assisted reproductive techniques (ART) days in the 1980s till the release of the Legislation Review Committee Report (Lockhart Report) in 2005

<sup>2</sup> Andrews Report at xxviii

However, a majority of the states supported SCNT, notably Victoria and Queensland, both of which were also important centres for stem cell research. During the COAG meeting in May 2006, the Federal and the New South Wales Governments resisted pressure from other states to change the moratorium on SCNT. However, under pressure to allow more discussion on the controversial issues raised in the Lockhart Report, the then Prime Minister, John Howard, said that he would allow a conscience vote in Parliament. A private member's bill was prepared by Senator Kay Patterson.<sup>3</sup> The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the *Amendment Act 2006*)<sup>4</sup> aimed to amend and broaden the scope of activities permitted under both Acts and, most notably to permit the use of embryos created specifically for research through SCNT. The formal and structured debates in Parliament where controversial issues are fully argued are evidence of regulatory legitimacy.

The House of Representatives witnessed fierce debate. It voted 82 for and 62 against. Members who supported the bill raised the following points:

- The bill would provide hope to the sick as some of them have loved ones with dreadful diseases;<sup>5</sup>
- It would stem the brain drain argument of Australian scientists leaving for greener pastures;<sup>6</sup>
- A reference was made to Professor Ian Fraser, the Australian of the Year, who urged people to support the bill;<sup>7</sup>
- A reference was made to Professor Loane Skene's proposal for the adoption of strict and transparent licensing and reporting to Parliament as preferable to total prohibition;<sup>8</sup> and

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<sup>3</sup> Most of the information here is from Otlowski M, 'The Lockhart Report of Human Cloning and the Regulation of Research Involving Human Embryos: An Overview' (2006) *Health Law Bulletin* 23-24

<sup>4</sup> An electronic version of the Act is available in <http://www.comlaw.gov.au>

<sup>5</sup> Ms.Grierson, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006, 151

<sup>6</sup> Mr Snowdon, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006, 137

<sup>7</sup> Mr Gibbons, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006, 169

<sup>8</sup> Mr Entsch, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006, 178

- While total agreement was impossible, the Bill found an acceptable middle ground with safeguards that addressed most concerns.<sup>9</sup>

Members against the bill raised the following points:

- There was obfuscation and deception in the terminology aimed to confuse, mislead and deceive people;<sup>10</sup>
- The bill was pushing out the boundaries that members were then told had reached their threshold in 2002;<sup>11</sup>
- It was offering false hope to sick people;<sup>12</sup>
- It might lead to a slippery slope to more contentious research;<sup>13</sup>
- There were insufficient eggs;<sup>14</sup>
- There was a worry about where society was heading, with reference to the *Brave New World* of Aldous Huxley;<sup>15</sup>
- There was a worry that the product of SCNT was in fact a cloned embryo because it could develop into a foetus and be implanted;<sup>16</sup>
- The ends were justifying the means;<sup>17</sup>
- There had been no discoveries that could support an urgent need for SCNT since the licensing system came into place in 2002;<sup>18</sup> and
- With limited funding, the most efficient path that delivers the best results and outcomes should be taken.<sup>19</sup>

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<sup>9</sup> Ms Owens, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 140

<sup>10</sup> Mr Murphy, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 123

<sup>11</sup> Mr Pyne, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 163

<sup>12</sup> Mr Murphy, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 124

<sup>13</sup> Ms Owens, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 142

<sup>14</sup> Mr Anderson, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 134

<sup>15</sup> Mr Causley, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 167

<sup>16</sup> Mr Fawcett, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 158

<sup>17</sup> Mr Tanner, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 154

<sup>18</sup> Mr Gavan, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 161

<sup>19</sup> Mr Ripoll, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 176

In the Senate, there was also fierce debate. It was divided with a vote of 34 for and 32 against. The senators who were in favour of the bill raised the following arguments:

- Reference was made to the history of medical science where research findings were not determined at the outset such as the development of cervical cancer vaccine by Professor Ian Frazer which would not have been possible if the moratorium had gone ahead in the 1970s;<sup>20</sup>
- Making reference to the risky experiment by Edward Jenner in 1796 by injecting cowpox into the arm of a young man that led to the discovery of smallpox vaccine;<sup>21</sup>
- That all medical research takes time to develop and reference was made to Ian Frazer's work which took more than 20 years;<sup>22</sup>
- That extra onus should be on those who were against SCNT research to justify the reasons to prohibit the activity;<sup>23</sup>
- That with adequate safeguards and penalties imposed by the law, there is no fear of the regeneration of 'Frankensteins' and other 'mad scientists';<sup>24</sup> and
- That it was the role of senators as legislators to set parameters around the moral and ethical issues.<sup>25</sup>

The senators who were against the bill raised the following concerns:

- Issues about the sourcing of human eggs for SCNT purposes;<sup>26</sup>
- Permitting SCNT would mean that scientists were crossing the ethical boundary and once crossed there would be no turning back;<sup>27</sup>

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<sup>20</sup> Senator Wong, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 4

<sup>21</sup> Senator Brown, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 9

<sup>22</sup> Senator McLucas, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 13

<sup>23</sup> Senator Bartlett, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 22

<sup>24</sup> Senator Murray, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 28

<sup>25</sup> Senator Sherry, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 30

<sup>26</sup> Senator Ellison, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 1

<sup>27</sup> Senator McGauran, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 16

- That there had not been any significant change in the state of play since 2002;<sup>28</sup>
- That the ethical parameters were not fully clarified in the debate and therefore impossible to put in place adequate policy to cover the concerns;<sup>29</sup>
- That the bill was put in such a haste and in absolute vacuum of evidence;<sup>30</sup> and
- That the Lockhart Report omitted three important detailed reports of the US President's Council on Bioethics (2002, 2004 and 2005).<sup>31</sup>

The *Amendment Act 2006* came into force on 12<sup>th</sup> June 2007. Schedule 1 of this Act amends the *PHC Act 2002*, Schedule 2 amends the *RIHE Act 2002*, Schedule 3 provides for saving provisions on existing licences already issued, and Schedule 4 provides for the amendment of regulations of the *Customs (Prohibited Exports) Regulations 1958*. Interestingly, the Act does not use of the words 'SCNT' and 'therapeutic cloning'. The probable reason was that other technologies besides SCNT were emerging and the adoption of an encompassing phrase was therefore more appropriate. In addition, technologies change and all embryos, however created, ought to be captured by the legislation. In Brownsword's terms, this encompassing phrase would enable judges to achieve regulatory connection, one of the regulatory challenges.<sup>32</sup>

In addition, the wording of many sections of the Act was amended by adding the phrase 'or by other means'. This was to clarify that the *Amendment Act 2006* regulates activities involving not only uses of embryos created by ART but also the creation and use of embryos created by other means, including SCNT.<sup>33</sup>

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<sup>28</sup> Senator Polley, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 20

<sup>29</sup> Senator Hurley, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 27

<sup>30</sup> Senator Santoro, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 35

<sup>31</sup> Senator Fierravanti-Wells, Commonwealth, Senate, *Parliamentary Debates*, Hansard, 7 November 2006 at 39. Professor Skene explained to him that time did not permit detailed inquiry into relevant literature; see 39

<sup>32</sup> See Chapter 3.2.3 of this thesis

<sup>33</sup> Phrases like 'other embryos and human eggs' were added in various sections of the Act

The provisions of the main amendments are discussed below, followed by a discussion of the major revisions made in the guidelines, the *National Statement* and the *ART guidelines*. In addition, many states and territories enacted complementary state legislation, mirroring the Commonwealth legislation. Collectively, the amendments made to the legislation, national and state/ territory, and revisions made to the guidelines ensure regulatory connection.

### 5.3 PROHIBITIONS WHICH REMAIN UNCHANGED

It is noted that there are prohibitions which remain unchanged. The status quo positions adopted for these prohibitions are in accordance with the recommendations put forward in the Lockhart Report which were based on the general views expressed in the submissions and forums. They include the following:

- Placing a human embryo clone in the human body or the body of an animal (Section 9 of *PHC Act 2002*);<sup>34</sup>
- Importing or exporting a human embryo clone (Section 10 of *PHC Act 2002*);
- No defence that the human embryo clone does not survive (Section 11 of *PHC Act 2002*);
- Creating a human embryo by fertilisation or a human egg by human sperm for a purpose other than achieving pregnancy in a woman (Section 12 of *PHC Act 2002*);<sup>35</sup>
- Creating and developing a human embryo by fertilisation of human egg by human sperm which contains genetic material provided by more than two persons (Section 13 of *PHC Act 2002*);<sup>36</sup>
- Developing a human embryo outside the body of a woman for more than 14 days (Section 14 of *PHC Act 2002*);<sup>37</sup>
- Making heritable alterations to a human genome (Section 15 of *PHC Act 2002*);

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<sup>34</sup> This reflects Recommendation 2 of Lockhart Report

<sup>35</sup> This reflects Recommendations 12 and 13 of Lockhart Report

<sup>36</sup> This reflects Recommendations 13 and 26 of Lockhart Report

<sup>37</sup> This reflects Recommendation 4 of Lockhart Report

- Collecting a viable human embryo from the body of a woman (Section 16 of *PHC Act 2002*);<sup>38</sup>
- Creating and developing a chimeric embryo (Section 17 of *PHC Act 2002*);<sup>39</sup>
- Developing a hybrid embryo beyond 14 days (Section 18 of *PHC Act 2002*);<sup>40</sup>
- Placing a human embryo in animal, a human embryo into the body of a human other than into the female reproductive tract or an animal embryo in a human (Section 19 of *PHC Act 2002*);<sup>41</sup>
- Importing, exporting or placing in the body of a woman a prohibited embryo (Section 20 of *PHC Act 2002*);<sup>42</sup> and
- Commercial trading in human eggs, human sperm or human embryos (Section 21 of *PHC Act 2002*).<sup>43</sup>

These prohibitions remained unchanged since 2002 and reflected the strong views against these activities still held by the Australian society as expressed in the Lockhart Report.

## **5.4 ACTIVITIES PERMITTED BY THE *AMENDMENT ACT 2006***

The *Amendment Act 2006* extends the scope of the *RIHE Act 2002* by allowing additional activities to be carried out under licence issued by the Licensing Committee. Division 2 of the *Amendment Act 2006* amends the *RIHE Act 2002*, providing for practices that are prohibited unless authorised by a licence. A person may now apply for a licence for the following:<sup>44</sup>

- The use of excess ART embryos (position unchanged);<sup>45</sup>

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<sup>38</sup> This reflects Recommendation 11 of Lockhart Report

<sup>39</sup> This reflects Recommendation 6 of Lockhart Report

<sup>40</sup> This reflects Recommendations 17 and 24 of Lockhart Report

<sup>41</sup> This reflects Recommendation 7 of Lockhart Report

<sup>42</sup> This reflects Recommendation 41 of Lockhart Report

<sup>43</sup> This reflects Recommendation 33 of Lockhart Report

<sup>44</sup> These are found in section 20(1) of *RIHE Act 2002*

<sup>45</sup> Section 10(1) of *RIHE Act 2002*

- The creation of human embryos by a process other than by fertilisation of a human egg by a human sperm and the use of use embryos, for instance SCNT;<sup>46</sup>
- The creation of human embryos, by a process other than fertilisation of human egg by human sperm, containing genetic material provided by more than 2 persons and use of such embryos;<sup>47</sup>
- The creation of human embryos using precursor cells from a human embryo or a human foetus and use of such embryos;<sup>48</sup>
- Undertaking of research and training involving the fertilisation of a human egg, up to but not including the first mitotic division, outside the body of a woman for the purposes of research or training;<sup>49</sup> and
- The creation of hybrid embryos by the fertilisation of a an animal egg by human sperm, and develop such embryos up to, but not including, the first mitotic division, provided that the creation or use is for the purposes of testing sperm quality and will occur in an accredited ART centre.<sup>50</sup>

It is important to stress that the Act continues to provide that the use of embryos is only authorised for development up to the first mitotic division or the stage at which the primitive streak appears, that is, around 14 days after fertilisation.<sup>51</sup> While the extension of the scope of the *RIHE Act 2002* by permitting additional activities, these additional activities also require licences issued by the Licensing Committee with the statutory safeguards and limitations.

## **5.5 OTHER AMENDMENTS MADE BY THE *AMENDMENT ACT 2006***

### **5.5.1 DEFINITION OF ‘HUMAN EMBRYO’ AMENDED**

According to the Lockhart Report, the original statutory definition of ‘human embryo’ had the unintended consequence of impending research. The intended

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<sup>46</sup> Section 10A(b)(i) of *RIHE Act 2002*. This reflects Recommendation 23 of Lockhart Report  
<sup>47</sup> Section 10A(b)(ii) of *RIHE Act 2002*. This reflects Recommendation 13 and 26 of Lockhart Report

<sup>48</sup> Section 10B of *RIHE Act 2002*. This reflects Recommendation 27 of Lockhart Report

<sup>49</sup> Section 10A(b)(iv) of *RIHE Act 2002*

<sup>50</sup> Section 9 of *PHC Act 2002*. This reflects Recommendation 17 of Lockhart Report

<sup>51</sup> Section 7 of the *RIHE Act 2002*



effect of the amendment was to bring more research activities, including SCNT, within the scope of the permitted activities.

Section 7(1) of the *RIHE Act 2002*, as amended by the *Amendment Act 2006*, now provides that a ‘human embryo’ is ‘as a discrete entity that has arisen from either:

- (i) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division.<sup>52</sup>

Paragraph (a) indicates that the identification of the first mitotic division as the time when fertilisation is complete and the time at which the fertilised egg becomes an embryo. This recognises that fertilisation is a process and an embryo does not arise until the process is complete.<sup>53</sup> Paragraph (b) refers to embryos created by means other than by fertilisation of human egg by sperm. The capacity to develop up to the stage of the appearance of the primitive streak is taken as the marker of an entity that it is an embryo. This is a conservative definition, and it is intended that paragraph (b) captures a human embryo created by the SCNT process and other future processes.<sup>54</sup>

The NHMRC arrived at this definition after establishing the Biological Definition of Embryo Working Party.<sup>55</sup> The definition differed slightly from the definition proposed in the Lockhart report where Recommendation 28 provided in (b) ‘... that has the potential to develop up to, or beyond, 14 days’. The Working Party proposed ‘... that has the potential to develop up to, or beyond, the stage at which

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<sup>52</sup> Section 7(1) of *RIHE Act 2002*

<sup>53</sup> Explanatory memorandum of *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* at 8

<sup>54</sup> Ibid. A parthenogenic human embryo is where a human egg is mechanically or chemically stimulated to undergo spontaneous activation and exhibit some of the characteristics of a fertilised human egg

<sup>55</sup> The Working Party comprised three Licensing Committee members and three other Australian experts

the primitive streak appears'. This proposed definition had been discussed with the Lockhart committee which had agreed on the change.<sup>56</sup>

### **5.5.2 SOMATIC CELL NUCLEAR TRANSFER PERMITTED**

Section 20(1)(b) of *RIHE Act 2002* was inserted to permit SCNT provided it is authorised by a licence issued by the Licensing Committee. This reflected Recommendation 23 of Lockhart report. This provision must be read in the context of two points. Firstly, the development of a human embryo outside the body of a woman for more than 14 days is prohibited.<sup>57</sup> Second, the placement in the body of a woman of a human embryo clone is prohibited.<sup>58</sup> The maximum penalty for failure to comply with this provision is ten years imprisonment.

SCNT is a controversial activity and this represents a liberalisation of the law. The conduct of SCNT is subject to stringent requirements which require a licence issued by the Licensing Committee.

### **5.5.3 CREATION OF CYBRIDS FOR SCNT RESEARCH PURPOSES REMAINS PROHIBITED**<sup>59</sup>

The creation of cybrids for SCNT purposes, where animal eggs instead of human eggs are used, is prohibited. Recommendation 24 was one of the few Lockhart recommendations which was not adopted in the *Amendment Act 2006*. Cybrids are controversial with strong opposition coming from pro-life groups, religious groups, especially from the Catholic faith,<sup>60</sup> and even some scientists are sceptical.

The prohibition of the creation of cybrids raises a serious concern. There is the problem of scarcity of human eggs, a vital ingredient for SCNT. With comprehensive guidelines on egg donation,<sup>61</sup> egg donors are now provided with

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<sup>56</sup> This is because the NHMRC had not finalised its recommended definition at the time that the Lockhart report was finalised in December 2005

<sup>57</sup> Section 16 of *PCH Act 2002*

<sup>58</sup> Sections 10 of *PCH Act 2002*

<sup>59</sup> There are other terms to describe this: 'cybrid' or 'chimera' or 'human-animal admixed embryo'

<sup>60</sup> Ms Owens, Commonwealth, House of Representatives, *Parliamentary Debates*, Hansard, 4 December 2006 at 141. She said she has received letters concerned about the use of animal eggs

<sup>61</sup> See later on the discussion of the updated *ART Guidelines 2007*

detailed information about health risks, short and long term, in egg extraction. The *ART guidelines* were revised to protect the interests of women, by including information on the various risks. It is unclear these revisions will lead to a deterrent effect on potential donors of eggs for SCNT research. As eggs are vital ingredients for SCNT research, without them, the conduct of the research is not possible.

In the United Kingdom, the *Human Fertilisation and Embryology Act 2009* legalises the creation of cybrids for SCNT purposes. It may be expected that, in Australia, when the legislation is reviewed again in 2010, this controversial issue will be redebated.<sup>62</sup> Australia may follow the UK's lead to resolve the problem of scarcity of human eggs for SCNT research.<sup>63</sup>

#### **5.5.4 DEFINITION OF 'UNSUITABLE FOR IMPLANTATION' INSERTED**

A new definition of 'unsuitable for implantation' was inserted<sup>64</sup> which includes a human embryo that:

- a) is diagnosed by preimplantation genetic diagnosis (PGD) as unsuitable for implantation, in accordance with the *ART Guidelines*; or
- b) is determined to be unsuitable for implantation in the body of a woman, in accordance with the objective criteria specified in guidelines issued under the *National Health and Medical Research Council Act 1992*.<sup>65</sup>

The effect of the insertion of a new definition of 'unsuitable for implantation' in the Act is that for the first time, it enables the use of fresh embryos in research, which would otherwise be discarded and this may prove to be another important source of embryos.

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<sup>62</sup> The *PHC Act 2002* and *RIHE Act 2002* will be reviewed three years after the amending Act comes into effect, that is, in 2010

<sup>63</sup> In UK, the *Human Fertilisation and Embryology Act 2008* permits the creation of cybrids for research purposes

<sup>64</sup> Section 7 of *RIHE Act 2002*

<sup>65</sup> This reflects Recommendations 20-22 of Lockhart Report

### **5.5.5 NO CRIMINAL LIABILITY FOR PERSON WHOSE CONDUCT WAS PURPORTEDLY AUTHORISED**

Section 12A is inserted in the *RIHE Act 2002*. It provides that a person is not criminally responsible for an offence against the Act in respect of particular conduct if:

- a) the conduct by the person is purportedly authorised by a provision of a licence; and
- b) the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and
- c) the person did not know and could not reasonably be expected to have known of the invalidity of licence or the provision.

This section was intended to address the underlying policy objective of Recommendations 50 and 51 of the Lockhart Report which recommend that the Licensing Committee should be given the power to give legally binding rulings on the interpretation of the legislation. Section 12A aimed to address the concern of the potential liability of a researcher who acts in good faith in accordance with a licence issued by the Licensing Committee. Recommendation 53 had provided that people who conduct research on the basis of a ruling should be protected from liability under the legislation.<sup>66</sup> Legal protection from liability is reasonable for researchers under such circumstances.

### **5.5.6 IMPORTING AND EXPORTING HESC LINES**

Section 23C of the *RIHE Act 2002* provides that the Minister who administers the *Customs Act 1901* must make appropriate regulations to permit the import and export of HESC lines derived from human embryo clones which have been derived using practices consistent with Australian legislation, that is, the cell lines must be ethically and legally derived.<sup>67</sup> This reflected Recommendation 42 of the Lockhart Report. This amendment ensured that there is consistency.

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<sup>66</sup> Explanatory memorandum of *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* at 28-29

<sup>67</sup> Explanatory memorandum of *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* at 22

### 5.5.7 FURTHER REVIEW OF THE ACT AND MINISTER TO REPORT TO PARLIAMENT<sup>68</sup>

Section 25 of *PHC Act 2002* and Section 47A of *RIHE Act 2002* provide that the Minister must cause a further independent review of the operation of Acts in three years after the *Amendment Act 2006* has received the Royal Assent, that is, in 2010<sup>69</sup> and a written report must be submitted to the Council of Australian Government and both Houses of the Parliament before the fourth anniversary of the day on which the amending Act received the Royal Assent.<sup>70</sup> The report must consider the following:

- The scope and operation of the Acts taking into account developments in ART;
- Developments in embryonic stem cell research;
- Community standards;
- An analysis of international developments and legislation;
- An analysis of research resulting from the licences granted;
- National Stem Cell Centre and national register of donated excess ART embryos;
- An evaluation of the effectiveness of the legislative provisions and guidelines relating to proper consent;
- An evaluation of the range of matters for which the Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation;
- An analysis of any research or clinical practice which has been prevented as a result of legislative provisions;
- The extent to which the Licensing Committee has effectively used information and education tools to assist researchers working in the field and any ongoing need for legally binding rules; and
- The extent of Commonwealth/ State cooperation in the area of human embryo research and the requirement for the Commonwealth or State legislation on the matter.<sup>71</sup>

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<sup>68</sup> This reflects Recommendation 53 of Lockhart Report

<sup>69</sup> Section 47A(1) of *RIHE Act 2002*

<sup>70</sup> Section 47A(3) of *RIHE Act 2002*

<sup>71</sup> Section 47A(4) of *RIHE Act 2002*

The report must contain recommendations about amendments that should be made to the Acts.<sup>72</sup> The committee undertaking the review must consult the Commonwealth and the States and a broad range of persons with expertise in or experience of relevant disciplines and their views must be set out in the report.<sup>73</sup> It is noted that it is the same committee that will undertake the reviews of both Acts. This amendment is clearly directed to ensuring regulatory connection of the law with the science and technology.

## **5.6 THE REVISED NHMRC GUIDELINES AND THE DEVELOPMENT OF FRESH GUIDELINES**

The *Research Involving Human Embryos Regulations 2003 (RIHE Regulations 2003)* prescribes the NHMRC guidelines that the LC must have regard to when issuing a licence. These are the *National Statement 1999* and the *ART guidelines 2004*. These are comprehensive guidelines, which together with legislation, reflect two rungs of Braithwaite's regulatory options pyramid, illustrating that effective regulation of controversial activities, like HESC research have no single regulatory solution.

As a result of the *Amendment Act 2006*, the NHMRC revised both the *National Statement* and the *ART guidelines*. In addition, the third set of fresh guidelines, the *Objective Criteria for Embryos Unsuitable for Implantation Guidelines 2007* (the *Objective Criteria 2007*) has been developed by the NHMRC. It is noted that revisions made to the *National Statement* and *ART guidelines*, as well as the development of the *Objective Criteria*, ensure regulatory connection.

### **5.6.1 THE REVISED NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH 2007<sup>74</sup>**

The *National Statement 2007* contains Australia's primary guidelines for the ethical conduct of research involving human participants. It is one of the key documents that support the new legislative regime arising from the passage of the *Amendment*

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<sup>72</sup> Section 47A(5) of *RIHE Act 2002*

<sup>73</sup> Section 47A(6) of *RIHE Act 2002*

<sup>74</sup> [www.nhmrc.gov.au/PUBLICATIONS/synposos/\\_files/e72.pdf](http://www.nhmrc.gov.au/PUBLICATIONS/synposos/_files/e72.pdf). It was co-issued by the NHMRC, the Australian Research Council and the Australian Vice-Chancellors' Committee

*Act 2006*. The values stated in these guidelines provide a comprehensive framework of principles to guide the design, review and conduct of human research. There are five sections in the *National Statement 2007* which are:

- Section 1 on the values and principles of ethical conduct;
- Section 2 on the themes in research ethics: risk & benefit and consent;
- Section 3 on ethical considerations specific to research methods or fields;
- Section 4 on ethical considerations specific to participants including the category of people in dependent or unequal relationships;<sup>75</sup> and
- Section 5 on the processes of research governance and ethical review.

It is noted that a public consultation was held before the revised National Statement was finalised,<sup>76</sup> and this ensures regulatory legitimacy.

Two important revisions made in the *National Statement 2007* are as follows:

- The chapter on the requirements for consent was revised significantly with extensive guidance on consent;<sup>77</sup> and
- A section on human stem cells was incorporated<sup>78</sup>

The general principles of consent are found in chapter 2.2, and include:

- Renegotiating consent especially where projects are complex and long-running;<sup>79</sup>
- Coercion and pressure to participate in research;<sup>80</sup>
- Reimbursement for participants in research;<sup>81</sup>
- Where other people need to be involved in cases where the participant is vulnerable and lacks the capacity to consent, for instance, people who are highly dependent on medical care and people with cognitive impairment;<sup>82</sup>
- Consent to future use of data and tissue in research;<sup>83</sup> and

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<sup>75</sup> *National Statement 2007* at 59

<sup>76</sup> <http://www.nhmrc.gov.au/research/embryos/information/index.htm>

<sup>77</sup> The significant changes on consent are made in Chapter 2.2 at 19-21

<sup>78</sup> Chapter 3.6 at 47

<sup>79</sup> Guideline 2.2.8

<sup>80</sup> Guideline 2.2.9

<sup>81</sup> Guideline 2.2.10, 2.2.11

<sup>82</sup> Guideline 2.2.12

<sup>83</sup> Guideline 2.2.14 -2.2.18

- Declining to consent and withdrawing consent.<sup>84</sup>

In the section on human stem cells, it has provisions on:

- Beneficence: This provides that researchers should have no involvement in the clinical care of the woman from whom an egg, embryo or foetus is obtained and the research should be conducted in a location that maintains a separation of the woman's clinical care from research;<sup>85</sup>
- Respect to egg/ embryo donors: this provides that the researcher should offer explanations to the donors on matters such as the following: (a) the research for which the stem cells are to be used (b) the implication of removing identifiers from stem cells, that is, the donors are no longer identifiable, including a loss in a say in the use of the stem cells and loss of the use for medical treatments for them and their relatives, (c) that they are free to decline to participate in research and entitled to withdraw from research at any time, (d) that the research could result in the production of stem cell line that could be maintained for many years and distributed to other countries and used in various research projects, (e) that they will not benefit financially from any future commercialisation of cell lines and they have no authority over any cell lines once identifiers are removed;<sup>86</sup>
- Conscientious objection by participants: this provides that people should not be compelled to participate or put at a disadvantage position because of their objection;<sup>87</sup> and
- Imported stem cell lines: this provides that where cell lines are imported from other countries, the researchers should attempt to establish whether there are ethical and professional policies in that country or institution governing the collection of the cell lines for research.<sup>88</sup>

These revisions protect the interests of research participants which include embryo and egg donors in HESC research. In addition, these changes are the result of the *Amendment Act 2006* and aim to ensure regulatory connection.

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<sup>84</sup> Guideline 2.2.19 – 2.2.20

<sup>85</sup> Guideline 3.6.5

<sup>86</sup> Guideline 3.6.6

<sup>87</sup> Guideline 3.6.7

<sup>88</sup> Guideline 3.6.8



### **5.6.2 THE UPDATED *ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNIQUES (ART) IN CLINICAL PRACTICE AND RESEARCH 2007***<sup>89</sup>

In 2007, revisions were made to the *ART Guidelines*. The changes are only to the extent made necessary by the amendments made by the *Amendment Act 2006*. Making such revisions ensure consistency between guidelines and legislation and also maintain regulatory connection. As the *Amendment Act 2006* now permits SCNT activity, it is important that the interests of egg donors for this activity are fully protected.

Ethical issues surrounding exploitation of women in egg donation for SCNT purposes were fully explored in the Lockhart Report. The Hwang scandal raised some serious concerns about exploitation of women in research.<sup>90</sup> It was therefore crucial that the guidelines pertaining to egg donation are updated and comprehensive in order to protect the interests of egg donors.

Recommendations 32 and 33 in the report are reflected in the revised *ART Guidelines*.<sup>91</sup> They incorporated detailed guidelines for egg donation to protect the interests of egg donors.

It is noted that the guidelines were updated by AHEC and they were released for public consultation. 93 submissions were received and these were analysed by a sub-group of AHEC. The NHMRC considered the revised draft.<sup>92</sup>

The revised guidelines do not adopt phrase SCNT, for instance, ‘... created by means other than by fertilisation of a human egg by human sperm’.<sup>93</sup> In addition, there is no reference to egg or oocyte. A more generic term is adopted, that is gamete, as the guidelines are intended to cover sperm donors as well.

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<sup>89</sup> The website is [http://www.nhmrc.gov.au/publications/synopses/\\_files/e78.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/e78.pdf). It was issued on June 2007

<sup>90</sup> The Hwang scandal was explored in Chapter 1.4.2 of this thesis

<sup>91</sup> Recommendation 31 is on the current principles of consent for participation in medical research to continue, Recommendation 32 is on the development of guidelines on egg donation and Recommendation 33 is on the reimbursement to egg donors

<sup>92</sup> See Appendix B of the *ART Guidelines 2007* at 87

<sup>93</sup> See the heading at 75

Section 17.21 provides that a person who agrees to her eggs being used in research is a research participant for the purposes of the *National Statement*.<sup>94</sup> Consent to the use of stem cells developed from donated eggs must meet the requirements of the section on human stem cells in the *National Statement*.<sup>95</sup> Any research involving procedures that carry significant risk of harm must be reviewed by HREC,<sup>96</sup> for instance, the risks of long term consequences of fertility must be disclosed to potential donors.<sup>97</sup> The HREC and the Licensing Committee must have regard to whether the donors have been fully informed about the risks to fertility and have given consent.<sup>98</sup> The HREC must be satisfied that the potential benefits are sufficient to justify the risks associated with the donation process. In deciding whether there is sufficient benefit, HRECs must apply the guidelines on risk and benefit in the *National Statement*.<sup>99</sup> Clinicians and clinical centres should encourage studies on the medical and psychological effects on the donors with a view to achieving more accurate evaluation of risk and benefit.<sup>100</sup>

The revisions made to the revised *ART Guidelines 2004* comprise three areas of importance. First, on the issue of consent, the revised guidelines emphasise that donation of eggs must be voluntary and free from exploitation or coercion.<sup>101</sup> To ensure the protection of egg donors, the guidelines provide comprehensive provisions. The potential donor should be provided with the following information both in oral and written form:

- A brief description of the project in lay language;
- A clear statement that the provision of her eggs is voluntary;
- A description of the intended use of her eggs;
- That any value for the eggs may only be realised in the long term;
- A description of the retrieval process of eggs including what will be done; where the procedure will be done and by whom;
- A statement of the potential risks of retrieving and donation of eggs;

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<sup>94</sup> Section 17.21 of *ART Guidelines 2007*

<sup>95</sup> Section 17.21.7 of *ART Guidelines 2007*

<sup>96</sup> Section 17.21.10 of *ART Guidelines 2007*

<sup>97</sup> Section 17.21.11 of *ART Guidelines 2007*

<sup>98</sup> Section 17.21.12 of *ART Guidelines 2007*

<sup>99</sup> Section 17.21.13 of *ART Guidelines 2007*

<sup>100</sup> Section 17.21.17 of *ART Guidelines 2007*

<sup>101</sup> Section 17.21.5 of *ART Guidelines 2007*

- A description of how to withdraw from egg donation;
- Her right to refuse donation for a specific project but agree to donation for another;
- A statement about the availability of counselling resources;
- How privacy will be protected;
- A statement of the potential financial and on financial interest of researchers;
- A statement that the donor will receive no financial benefits;
- A statement that the donation will not be used for any other purpose;
- A statement of any future financial gains that the researcher may receive if the research gives rise to a commercial product; and
- Any other information required by the *National Statement 2007*.<sup>102</sup>

Counselling on the risks and the psychological and ethical implications of donation must be offered to the donors, and the counsellors should be available at any time from before the procedures for retrieval of eggs are commenced to the time they are used in research.<sup>103</sup> The number of cycles and intensity of ovarian stimulation should be limited.<sup>104</sup> An egg donor may withdraw consent<sup>105</sup> and is entitled to know the outcome of the research.<sup>106</sup>

Secondly, women who are in dependent relationships should not be permitted to be egg donors. These include relationships between researchers and students or other junior staff employed at a research institute.<sup>107</sup> Thirdly, the statutory prohibition on selling eggs<sup>108</sup> is reiterated in the updated guidelines.<sup>109</sup> However, reimbursement of reasonable out-of-pocket expenses associated with the procedures is permitted for

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<sup>102</sup> Section 17.21.6 of *ART Guidelines 2007*

<sup>103</sup> Section 17.21.15 of *ART Guidelines 2007*

<sup>104</sup> RTAC Code of Practice, code of practice for assisted reproductive technology units (RTAC 2005), which is developed by the profession for the accreditation of the ART centres in Australia

<sup>105</sup> Section 17.21.8 of *ART Guideline s2007*

<sup>106</sup> Section 17.21.9 of *ART Guidelines 2007*

<sup>107</sup> Section 17.21.5 of *ART Guidelines 2007*. There are explanations of ‘dependent relationship’ at 59 of the *National Statement 2007*

<sup>108</sup> Section 23 of *PHC Act 2002*

<sup>109</sup> Section 17.21.2 of *ART Guidelines 2007*

egg donors for the discomfort, inconvenience and risks associated with the surgical removal of eggs.<sup>110</sup>

The updated guidelines pertaining to egg donation as explored above are comprehensive and adequately protect the interests of egg donors. Had similar stringent and comprehensive regulation existed in South Korea, the Hwang scandal might have been prevented.

It is noted that the Lockhart committee conducted the law review in 2005 which was at the same time when the Hwang scandal was exposed. Thus, there were concerns raised about exploitation of women in SCNT research in the submissions made to the committee. These concerns were taken into consideration when the recommendations were made and they in turn have led to the revisions of the *ART Guidelines 2004* which currently provides adequate protection to egg donors as discussed above. This provides evidence that the conduct of law reviews periodically are crucial as they would assist in ensuring regulatory connection.

### **5.6.3 DEVELOPMENT OF NEW GUIDELINES: *THE OBJECTIVE CRITERIA FOR EMBRYOS UNSUITABLE FOR IMPLANTATION GUIDELINES 2007***<sup>111</sup>

The *Amendment Act 2006* includes a definition of ‘unsuitable for implantation’, and requires the development of guidelines containing the objective criteria for determining when embryos are unsuitable for implantation. This reflects Recommendations 20 and 21 of the Lockhart Report.

According to the *Objective Criteria 2007*, embryos which are unsuitable for implantation, determined by a qualified embryologist, include:

- A blastocyst with no inner cell mass
- A blastocyst with 80% or more fragmentation
- A blastocyst with 80% or more degeneration,
- A blastocyst with 80% or more vacuoles, that is fluid filled space

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<sup>110</sup> Ibid

<sup>111</sup> Further information on the *Objective Criteria 2007* is found at Appendix 1 of NHMRC’s Information Kit

- A blastocyst with no compaction, that is, cells fail to merge
- Any embryo that has not divided within 24 hours
- Any embryo with 80% or more multinucleated blastomeres

The *Objective Criteria 2007* were released for public consultation in March 2007 in accordance with the requirement of the *NHMRC Act 1992*. Consultation was undertaken with experts to finalise the *Objective Criteria 2007* for consideration by the NHMRC Council. The Council recommended that the *Objective Criteria 2007* be issued as guidelines by the CEO. These criteria were endorsed by the Scientists in Reproductive Technology (SIRT) Committee and they must be used for determining embryos that are considered unsuitable for implantation and that may be used for research. The NHMRC will continue to work actively with the scientific community to update and further refine these *Objective Criteria 2007* as additional scientifically authenticated information becomes available.

The development of fresh guidelines containing the objective criteria for determining when embryos are unsuitable for implantation is essential as the criteria clarify the definition of such fresh embryos, which are another important source of embryos, in research. Thus, it is evident that the development of these new guidelines ensure regulatory connection.

## **5.7 CORRESPONDING STATE AND TERRITORY LEGISLATION SUBSEQUENT TO THE *AMENDMENT ACT 2006*<sup>112</sup>**

Under the COAG agreement of April 2007, all states and ACT, except Northern Territory, restated their commitment to introduce nationally consistent legislation into their respective parliaments. The change in state law is intended to avoid potential legal complications, such as constitutional gap since it is possible that there are activities that fell outside the jurisdiction of the federal Parliament. In addition to achieving consistency with federal legislation, the change in state legislation illustrates regulatory connection. However, Western Australia has rejected the Bill despite having made a commitment under the COAG agreement.

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<sup>112</sup> See Appendix 6 of this thesis

This situation presents legal difficulties for researchers who intend to embark on such research in that state.

## 5.8 CONCLUSION

The Australian regulatory framework on cloning and stem cell technology, after considerable debate in 2002, is one that has evolved with the changing times. Its regulatory connection, in Brownswords' terms, to a great degree was effected by the legislation review of the Lockhart committee and the Heerey committee. The national Acts of *PHC Act 2002* and *RIHE Act 2002* have provisions for mandatory review of the law that led to the appointment of the Legislation Review Committee and the release of Lockhart Report in 2005 and the Heerey Report in 2011. The rapid implementation of the recommendations in the report is also important as evidenced in the enactment of the *Amendment Act 2006* in the subsequent year and among the significant changes in the law were legalising the conduct of SCNT research under strict conditions and permitting fresh ART embryos that are unsuitable for implantation to be used in research.

In addition to amendments to the Acts, the National Guidelines, the *National Statement 1999* and the *ART Guidelines 2004*, were revised in 2007 to reflect the amendments made in the Acts. In the same year, fresh guidelines, the *Objective Criteria 2007*, was developed by the NHMRC as recommended in the Lockhart Report which would determine when the embryos are unsuitable for implantation and thus are available as another source of embryos for research.

The *Amendment Act 2006* too has a statutory provision on mandatory legislation review and the imminent review will be conducted at the end of this year, 2010. This will ensure that the legislation and guidelines will always keep pace with the dynamic, fast paced changing science.

From these piecemeal developments, it is evident that the Australian regulatory regime on cloning and stem cell technology, principally through the statutory provisions for mandatory review of both Acts, is responsive and maintains regulatory connection. The responsiveness reflects the Andrews Report, which

provided that ‘the regulatory framework must be transparent, accountable and responsive.’<sup>113</sup> Collectively, the previous chapter, this chapter and the next chapter illustrate the importance of provisions in the Acts that provide for a mandatory law review to be conducted within three years. This chapter also illustrates the equal importance of the implementation of the recommendations in the report by the enactment of amending legislation and revisions of the NHMRC guidelines. These amendments and revisions collectively ensure regulatory connection of the legislation with scientific developments.

The next chapter explores the extent to which the Australian regulatory regime on cloning and stem cell research achieves regulatory effectiveness with reference to the assessment of the licensing system, an important component of the regulatory framework.

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<sup>113</sup> Andrews Report at xxviii

## **6: REGULATORY EFFECTIVENESS IN ACTION: THE LICENSING SYSTEM FOR USE OF HUMAN EMBRYOS**

### **6.1 INTRODUCTION**

This chapter explores the extent to which the Australian regulatory model for use of human embryos, which incorporates the strict statutory licensing scheme, achieves regulatory effectiveness. Regulators achieve regulatory effectiveness when their intervention works and as Brownsword explains, ‘regulators should consider the necessity for making an intervention, that they need to be clear about their objectives and smart in their approach, and that the more that regulators are able to act with the grain of regulatees’ values, the more likely it is that their intervention will be effective.’<sup>1</sup> As it is recommended that Malaysia should formulate an effective framework to regulate human embryonic stem cell (HESC) research, the detailed description as well as critical analysis of Australia’s licensing system in this chapter could assist Malaysia in its design of a framework that incorporates a similar system.

This chapter explains key features and operations of the Embryo Research Licensing Committee of the National Health and Medical Research Council (NHMRC) (LC). It explains the committee’s membership, functions, powers, operations including the issue of licence, the imposition of licence conditions, variation/ suspension/ revocation of licence and monitoring compliance. It also explains reviews and appeals by applicant for licences, offences under the Act, transparency and cost recovery mechanism.<sup>2</sup>

The chapter concludes with a critique of various aspects of the licensing system with references made to the Legislation Review Committee Report (Lockhart Report).<sup>3</sup> It then explains the relevant recommendations in the Lockhart Report that would improve those aspects of the system as well as amendments made in the

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<sup>1</sup> See Chapter 3.2.2 of this thesis

<sup>2</sup> All of these licensing features are explained in the first part of this chapter, 6.2-6.8

<sup>3</sup> See Chapter 4.8 of this thesis which explains the background of this report



*Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the *Amendment Act 2006*) that modified the licensing system.<sup>4</sup> Critique and subsequent improvements to the licensing system will further ensure regulatory effectiveness.

## **6.2 MEMBERSHIP OF THE LICENSING COMMITTEE**

The Embryo Research Licensing Committee (LC) is a principal committee of the National Health Medical Research Council (NHMRC), established by the *Research Involving Human Embryo Act 2002* (Cth) (*RIHE Act 2002*).<sup>5</sup> Its structure and organisation are stipulated in the legislation. The first LC was appointed in 2003. Its members were appointed by the Federal Minister,<sup>6</sup> following extensive consultation with relevant State and Territory Ministers.<sup>7</sup>

It is essential that the composition of the LC comprises of members who come from a wide variety of background. Having diverse composition in the membership of any committee illustrates the concept of tripartism advocated by Braithwaite as an effective measure in deterring and controlling regulatory capture.<sup>8</sup> The composition of the committee prescribed in the legislation reflects this. It requires that committee members be drawn from a range of areas of expertise which include the following:<sup>9</sup>

- Research ethics;
- Public health research;
- Biotechnology law;
- Embryology;

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<sup>4</sup> The sources referred to in this chapter include *Research Involving Human Embryo Act 2002* (*RIHE Act 2002*), Lockhart Legislation Review Committee Report (Lockhart report 2005), *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the *Amendment Act 2006*), explanatory memorandum and NHMRC website

<sup>5</sup> Section 13 of *RIHE Act 2002*

<sup>6</sup> Section 16(2) of *RIHE Act 2002*

<sup>7</sup> Section 16(3) of *RIHE Act 2002*

<sup>8</sup> See Chapter 3.3.2 of this thesis

<sup>9</sup> Section 16 of *RIHE Act 2002*. This thesis notes that one of its former members, Dr Peter Illingworth, resigned in 2005 upon accepting employment at an IVF company. Section 16(3)(c) of the *RIHE Act 2002* provides that 'the Minister must be satisfied upon receipt of a written declaration by the member ... does not have a direct or indirect pecuniary interest in a body that undertakes uses of excess ART embryos, being an interest of a kind that could conflict with the proper performance of the member's functions'

- Consumer issues relating to assisted reproductive technology;
- Consumer health issues relating to disability and disease; and
- Regulation of assisted reproductive technology.

The LC of 2003-2006 triennium comprised nine members.<sup>10</sup> The same members were reappointed for a further three year period in 2006.

The Lockhart Report made various recommendations to expand the functions of the LC, which the Government accepted and incorporated into the *Amendment Act 2006*. Despite this, the Lockhart Report made no recommendations in relation to the LC's composition. The stated rationale for this was that the current membership is expressed relatively broadly in section 16 of *RIHE Act 2002*. Also, the CEO of the NHMRC has the capacity to appoint sub-committees in accordance with *NHMRC Act 1992*.<sup>11</sup> The present LC, appointed for 2009-2012 triennium, comprises of seven members with the appointment of two more members to be announced in the near future.<sup>12</sup> It also comprises of members drawn from a range of areas of expertise, thus preventing regulatory capture.

### **6.3 POWERS AND FUNCTIONS OF THE LICENSING COMMITTEE**

The LC is responsible for administering the national regulatory system described by the *RIHE Act 2002* and therefore plays an indispensable role in the regulation of human embryo research.<sup>13</sup> The Act regulates certain uses of excess human embryos created through assisted reproductive technology (ART), and makes it a criminal offence to use an excess ART embryo unless it is authorised by a licence issued by the LC. The *Amendment Act 2006* broadens the scope of activities permitted under the legislation, particularly allowing the use of human oocytes and the use of embryos created through somatic cell nuclear transfer (SCNT). The role of the LC is now extended to include the oversight of these additional activities.

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<sup>10</sup> Section 17 of *RIHE Act 2002*

<sup>11</sup> Explanatory Memorandum of *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* at 29

<sup>12</sup> <http://www.nhmrc.gov.au> (11 February 2010)

<sup>13</sup> Section 14 of *RIHE Act 2002* provides for the functions of the LC

The LC ‘has power to do all things necessary or convenient to be done for or in connection with the performance of its function.’<sup>14</sup> This general statutory provision provides the LC with wide discretionary powers to exercise especially in ambiguous areas not explicitly covered by the *RIHE Act 2002*.<sup>15</sup>

The LC has four main functions. First, the LC considers applications for licences to use excess ART embryos and SCNT embryos. This has been the substantial component of the LC’s work including applications to vary existing licences.

Secondly, the LC monitors compliance with the legislation through audits undertaken by appointed inspectors. The LC has the power to take enforcement, if required action such as cancelling and suspending licences.<sup>16</sup>

Thirdly, the LC engages in policy development. A significant example was made by the development of the discussion paper, ‘Human Embryo’—A Biological Definition (DP).<sup>17</sup> The DP was drafted in response to a request from the Council of the NHMRC. The definition proposed in the DP was subsequently adopted in the *Amendment Act 2006*.

Fourthly, the LC develops programmes of activities for communication with stakeholders. These activities have included:<sup>18</sup>

- Production of information kit to assist potential licence applicants<sup>19</sup>
- Production of information for prospective embryo donors<sup>20</sup>
- Production of information bulletins about the committee’s activities

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<sup>14</sup> Section 15 of *RIHE Act 2002*

<sup>15</sup> See the discussion in the later part of this chapter on the resolution proposed by the Lockhart Report in relation to some criticisms (namely criticisms 2,4,5 and 8 in 6.9 of this chapter) raised about the LC

<sup>16</sup> See section 6.6 of this chapter

<sup>17</sup> Findlay JK et al ‘Human Embryo: A Biological Definition’ (2007) 22 *Human Reproduction* 905-911. It is also available online at [http://www.nhmrc.gov.au/\\_files\\_nhmrc/file/research/embryos/reports/humanembryo.pdf](http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf) (11 February 2010). This DP was referred to extensively in Chapter 2.6 of this thesis

<sup>18</sup> These are mentioned in <http://www.nhmrc.gov.au/embryos/information/reports/index.htm>

<sup>19</sup> See <http://www.nhmrc.gov.au/publications/synopses/hc56.htm>

<sup>20</sup> The *RIHE Act 2002* established a regulatory system for the use of certain human embryos in research. This system provides couple who have spare embryos that were created for the ART treatment with the option of donating these embryos to research. The LC has produced a leaflet which explains this and other options that are available to couples in relation to embryos which are excess to their reproductive needs

- Presentations by members of the Committee at various meetings, visits to applicants by committee members and secretariat
- Conducting training workshop for human research ethics committee (HREC) members.

The information kit includes documents developed by the LC particularly the “objective criteria” for determining embryos that are unsuitable for implantation<sup>21</sup> and a consent checklist.<sup>22</sup> In developing policies, the LC has worked closely with the Australian Health Ethics Committee (AHEC).

These four main functions demonstrate the crucial role which the LC plays in the regulation of human embryo research and administering the national regulatory system in the *RIHE Act 2002*. These indispensable functions which the LC performs ensure regulatory effectiveness.

## 6.4 TRANSPARENCY

In ensuring regulatory effectiveness, transparency and accountability is an essential feature. Two mechanisms are provided in the *RIHE Act 2002* to ensure transparency. First, the LC is legally obliged to maintain a publicly available database.<sup>23</sup> The database is required to contain, in relation to each licence issued, the following information:

- The name of the organisation/ licence holder;
- A short statement about the project, that is, the nature of the uses of excess ART embryos/ other human embryos/ eggs;
- Conditions to which the licence is subject;
- The number of excess ART embryos/ other human embryos/ eggs authorised to be used under the licence;
- Date of issue of licence; and
- Date of expiry of licence.

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<sup>21</sup> Appendix 1 of Information Kit

<sup>22</sup> Appendix 6-8 of Information Kit

<sup>23</sup> Section 14(b) of *RIHE Act 2002*. The database is available on the NHMRC website. See [www.nhmrc.gov.au/embryos/monitor/database/index.htm](http://www.nhmrc.gov.au/embryos/monitor/database/index.htm)

Secondly, the LC is legally obliged to table half-yearly reports to the Parliament.<sup>24</sup> The report must include information about the operation of the Act and licences issued under the Act, and be tabled on or before 30<sup>th</sup> June and 31<sup>st</sup> December each year. A report must also be prepared at any other time as required by either House of Parliament.

However, there are some limitations and some information are confidential. These include applications for licences which are unsuccessful, objections by donors and confidential commercial information.<sup>25</sup> Nevertheless, it is submitted that the two mechanisms, operating an informative database and making regular reports to Parliament as described above, illustrate the important features of transparency in a controversial area, of research involving human embryos.

## **6.5 PROCEDURES FOR THE ISSUE OF LICENCE**

### **6.5.1 CRITERIA TO DETERMINE WHETHER A LICENCE SHOULD BE ISSUED<sup>26</sup>**

There are criteria the LC must consider before issuing licence authorising the use of human embryos, as set out by *RIHE Act 2002*. The regulatory scheme has features giving it, what Brownsword refers to as a restrictive tilt and not a permissive one, that is, it adopts a regulatory position which permits the practice ‘accompanied by reservations and qualifications’.<sup>27</sup>

At the first stage, applicants for licence must present their proposal to their institutional Human Research Ethics Committee (HREC) that must be satisfied that:

- The embryos are excess to the need of the couple in the ART programme;  
and
- All necessary consents have been obtained.

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<sup>24</sup> Section 19(3) of the *RIHE Act 2002*

<sup>25</sup> See Section 8 and Sections 29-30 of *RIHE Act 2002*. It is also noted that an Administrative Appeal Tribunal (AAT) case concerning the review of an application not successful is also not publicly available; see 6.5.6 of this chapter

<sup>26</sup> Section 21 of *RIHE Act 2002*

<sup>27</sup> Brownsword R, ‘Regulating Human Genetics: New Dilemmas for a New Millennium’ (2004) *Medical Law Review* 16 -17. He gave the example in UK where the Human Fertilisation Embryology Authority (HFEA) is mandated to license research on human embryos only if such research is judged to be necessary and this signals permission subject to negative reservation

When the HREC approves the proposal, the application can then be referred to the LC for consideration.

The LC must issue licences only where it is satisfied that:

- Appropriate protocols are in place regarding proper consent to be obtained before excess ART embryos, other embryos or eggs are used and to ensure adherence to any restrictions specified by the persons for whom the embryo was created;<sup>28</sup> and
- The proposed activity has been considered and approved by an HREC that is constituted in accordance with and acting in compliance with the NHMRC's *National Statement on Ethical Conduct in Human Research*;<sup>29</sup>

In addition, the LC must have regard to the following:

- The application is restricted to the number of excess ART embryos, other types of regulated embryos or eggs that are 'likely to be necessary to achieve the goals of the research or activity proposed in the application',<sup>30</sup>
- There is a 'likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos, other types of regulated embryos or eggs proposed in the application which could not reasonably be achieved by other means',<sup>31</sup> and
- Any relevant guidelines or part of guidelines issued by the NHMRC as prescribed in the Regulations have been followed.<sup>32</sup>

The LC has issued ten licences for embryo research, with nine of them currently active.<sup>33</sup> Six of them have been issued for the derivation of HESCs<sup>34</sup> and three of

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<sup>28</sup> Section 21(3)(a) of *RIHE Act 2002*

<sup>29</sup> Section 21(3)(c) of *RIHE Act 2002*

<sup>30</sup> Section 21(4)(a) of *RIHE Act 2002*

<sup>31</sup> Section 21(4)(b) of *RIHE Act 2002*

<sup>32</sup> Section 21(4)(c) of *RIHE Act 2002*

<sup>33</sup> Melbourne IVF surrendered their licence (a collaborative project with Stem Cell Science Pty Ltd) on 16 November 2009

<sup>34</sup> The other four licences are for embryo research, for instance, the development of testing procedures for unbalanced chromosome errors in human embryos

these are for the derivation of HESCs from excess ART embryos and three are for the attempted creation of embryos by SCNT.<sup>35</sup>

In Australia, there were 118,700 embryos in frozen storage in 2006.<sup>36</sup> All were intended to be used to achieve a pregnancy, and very few have been declared to be excess to ART requirements. Few couples with stored embryos have chosen to donate them for research at the present time.<sup>37</sup>

As for SCNT research, eggs considered to be unsuitable for use in clinical treatment are permitted to be used under the licences.<sup>38</sup> It is noted that few women have been willing to donate their eggs for research.<sup>39</sup>

### 6.5.2 ENSURING PROPER CONSENT IS OBTAINED

For the issue of a licence, consent is a pivotal requirement under the Act. Before issuing a licence, the LC must be satisfied that first, the consent protocols are appropriate, and secondly, the donors have appropriate information before them to enable them to make an informed decision on whether to donate the embryo to research.

It is illegal to use an excess ART embryo for licensed research without consent in writing by all 'responsible persons'. Section 24(1) of the *RIHE Act 2002* provides that, before an excess ART embryo is used as authorised by the licence, each responsible person (that is, all those involved in providing the egg or sperm for the creation of the embryo and any spouses)<sup>40</sup> must provide consent. The legislation prescribes a two-stage consent process: first, the consent that the embryo is excess;

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<sup>35</sup> All three licences are issued to Sydney IVF clinic where a total of 7,200 eggs are authorised to be used, that is, 2,400 eggs for each licence issued

<sup>36</sup> This is the most recent time for which data are available; see <http://www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/stem-cells-cloning-and-related-issues> (26 December 2011)

<sup>37</sup> McMahon C, 'Embryo Donation for Medical Research: Attitude and Concerns of Potential Donors' (2003) 18 *Human Reproduction* 871-877

<sup>38</sup> Face-to-face interview with Dr Robert Jansen, Medical Director of Sydney IVF Ltd, 30th October 2009, interview by Chee Kuen Foong (Patrick)

<sup>39</sup> See Chapter 1 of this thesis where it explains there are many health risks involved in the egg extraction procedures. See also Loane Skene's views in <http://www.essentialbaby.com.au/parenting/conception/donating-eggs-for-research-is-tough--so-why-not-pay-for-it-20090713-di3k.html> (18 June 2010). She favours payment to be made to egg donors as an incentive

<sup>40</sup> Section 8 of *RIHE Act 2002*

and, secondly, consent that the embryo may be used in research. Consent forms in ART clinics have been redrafted generally to comply with these two stages.

There are similar consent provisions for donors of other embryos and eggs. Counselling is required to be offered before consenting. Both oral explanation as well as written information describing the proposed use of the excess ART embryos, other types of regulated embryos or eggs must be provided to all responsible persons.

While consent is a requirement for the issue of licence, these stringent procedures demonstrate Brownsword's "restrictive tilt" making it difficult to use the embryos in research.

### **6.5.3 NOTIFICATION OF DECISIONS AND DURATION OF LICENCE**

The LC must inform its decision on an application for a licence to the applicant, the HREC and the relevant State body in which the use is to occur and copies of the licence must be given to the bodies.<sup>41</sup> The dates of the period of licence, date when the licence comes into force and expiry date, are specified in the licence.<sup>42</sup>

### **6.5.4 LICENCE CONDITIONS<sup>43</sup>**

Brownsword's restrictive tilt is also apparent in the two types of licence conditions imposed by the LC: standard and special conditions.

The LC has developed six standard conditions of licence. They apply to all licences and an exception is made if 'the special conditions for a particular licence provide a specific standard condition does not apply to that licence.'<sup>44</sup> The six conditions impose obligations on the licence holder to do the following:

- To give written notice of change in the contact details;
- To ensure persons authorised to participate in the licensed activity are fully informed of the requirements of the licence;

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<sup>41</sup> Section 22 of *RIHE Act 2002*

<sup>42</sup> Section 23 of *RIHE Act 2002*

<sup>43</sup> Section 24 of *RIHE Act 2002*

<sup>44</sup> <http://www.nhmrc.gov.au/index.htm> (11 February 2010)



- To report on various matters: These include preparing the report in the reporting period, reporting on non-compliance with licence conditions and reporting on any investigation and prosecution;
- To implement processes that ensure adequate record are stored, providing additional information when requested by the LC and providing reasonable assistance and cooperation to the LC;
- To maintain a tracking system that uniquely identifies each excess ART excess embryo/ egg/ other embryos created to a specific licence and each responsible person, record outcomes of each excess ART embryo/ egg/ other embryo created, link the outcomes to unique identifiers for each embryo or egg and review all consent forms prior to the expiry or surrender of the licence relating to embryos or eggs still in storage and deal with them in accordance with instructions; and
- To notify to the LC that proper consent has been obtained.

Special licence conditions relate to a particular licence. They operate in addition to standard conditions. Where there is an inconsistency between a special condition and a standard condition, the former prevails. Examples of special conditions imposed by the LC include conditions on:

- The number of excess ART embryos or eggs authorised for use;
- The number of other embryos authorised to be created or used;
- The people authorised to create and/or use them; and
- The authorised sites, as well as any other special conditions determined by the NHMRC Licensing Committee.

These two types of licence conditions illustrate the stringent and detailed requirements that need to be fulfilled by the researcher. The consequences of breaching the conditions could lead to revocation of the licence or other consequences discussed below.

### **6.5.5 VARIATION,<sup>45</sup> SUSPENSION OR REVOCATION<sup>46</sup> AND SURRENDER OF LICENCE<sup>47</sup>**

The legislation prescribes three ways in which issued licences may be modified. First, the LC may vary a licence if it believes on reasonable grounds that it is necessary or desirable to do so.<sup>48</sup> This may be the result of the LC's own initiative or on request by the licence holder.<sup>49</sup> Varying a licence may mean varying existing conditions or inserting additional conditions.<sup>50</sup> For instance, variation can extend the duration of a licence, change the number of embryos approved for use or alter the goals or objectives of the research.<sup>51</sup>

Secondly, the LC may suspend or revoke a licence if it believes on reasonable grounds that a condition of the licence has been breached.<sup>52</sup> If the licence holder is convicted of an offence under the Act, the LC revokes each licence held by the licence holder.<sup>53</sup>

Thirdly, the licence holder may surrender the licence to the LC, and this has occurred once.<sup>54</sup>

All of these acts must be by notice in writing to all parties concerned, the licence holder, the HREC and the relevant State body.<sup>55</sup>

### **6.5.6 REVIEWS AND APPEALS**

An applicant or licence holder may apply to the Administrative Appeals Tribunal (AAT) for a review of the LC's decision in the following matters:

- Not issuing a licence;
- Duration of the licence;
- Licence conditions;
- Varying or refusing to vary a licence; and

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<sup>45</sup> Section 25 of *RIHE Act 2002*

<sup>46</sup> Section 26 of *RIHE Act 2002*

<sup>47</sup> Section 27 of *RIHE Act 2002*

<sup>48</sup> Section 25(1) of *RIHE Act 2002*

<sup>49</sup> Section 25(2) of *RIHE Act 2002*

<sup>50</sup> Section 25(3) of *RIHE Act 2002*

<sup>51</sup> See LC's bi-annual reports to Parliament

<sup>52</sup> Section 26(1) of *RIHE Act 2002*

<sup>53</sup> Section 26(2) of *RIHE Act 2002*

<sup>54</sup> Section 27 of *RIHE Act 2002*

<sup>55</sup> Section 28 of *RIHE Act 2002*

- Suspending or revoking a licence.<sup>56</sup>

To date, there has only been one application for review before the AAT. This review was instituted in 2007, and involved the licence holder, Sydney IVF Limited, which sought a review of the LC's decision not to vary its licence. The licence holder applied for a variation to its existing licence,<sup>57</sup> that is, '... various subculture methods will be used to derive an optimum method of passaging the cells'.<sup>58</sup> The review is an unreported decision of the AAT.<sup>59</sup> The stated reasons for decision of the LC's were that the applicant had provided insufficient information and that the LC was not satisfied that the proposal in the application was going to lead to a significant advance in knowledge or improvement in technology or treatment. Having regard to additional information provided by the applicant both prior to and during the hearing, the parties reached an agreement that the LC would vary the licence.<sup>60</sup> The AAT issued orders, which gave effect to the agreement.<sup>61</sup> The AAT acknowledged that the original decision of the LC had been made on the basis of the information provided to it at that time and therefore, the tribunal stated that there was no criticism of the LC and the position it had taken to its original decision.<sup>62</sup>

The AAT noted there is a need for open communication of information by applicants. Applicants need to be clear about their intentions or project goals at the start and then the LC is clear about their scientific objectives, which enables it to make its decision. This was a case where a lack of information was causing a problem. To facilitate the information gathering exercise, the LC generally appoints a Working Group and the AAT noted:

... the way that the LC works is to appoint a working group from within its members who go and visit the applicants and sit around the table and try and work out what it is they want to do and try and tell them where the blanks are from the committee's point of view and come to some agreement about it ...

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<sup>56</sup> Section 32 of *RIHE Act 2002*

<sup>57</sup> Licence 309703

<sup>58</sup> Ibid

<sup>59</sup> Not publicly available- copy on file with the author

<sup>60</sup> National Health Medical Research Council, *Report to the Parliament of Australia*, for the period 1 October 2007 to 31 March 2008 at 6

<sup>61</sup> The orders were issued on 4 January 2008, *ibid*

<sup>62</sup> *Report to Parliament of Australia*, for the period 1 October 2007 to 31 March 2008 at 6

the working group then comes back to the LC with a recommendation but the final decision is the LC's decision.<sup>63</sup>

The LC emphasised that it was not concerned with minute detail of this project but the LC needed sufficient information in order for it to be able to justify the variation and therefore the use of the embryos.<sup>64</sup> Information provided to the LC should be clear and specific without being too general: 'You can't have a totally open-ended approval, it has to be divided somehow or other.'<sup>65</sup>

This review illustrates the need for applicants to provide information on the project or variation objectives to the LC, sufficient to enable it to make its decision.

## **6.6 MONITORING COMPLIANCE AND THE ROLE OF INSPECTORS**

Monitoring of activities undertaken by licence holders by inspectors is a crucial element of the scheme to fulfil the requirement of regulatory effectiveness as formulated by Brownsword.<sup>66</sup> The *RIHE Act 2002* sets up a monitoring and inspection system for facilitating monitoring compliance with the legislation.

The Chair of the LC appoints inspectors, which include a chief inspector and two ordinary inspectors.<sup>67</sup> The findings of inspectors' activities are reported to the LC and these reports are included in the six-monthly reports of the LC to Parliament. The inspectors also monitor compliance with the State and Territory legislation as each jurisdiction has agreed. The monitoring and compliance framework is based on a model of 'cooperative compliance', where licence holders are encouraged to cooperate with the LC to comply with the legislation.<sup>68</sup> To raise awareness of the responsibilities of both licence holders and inspectors, emphasis is placed on education and communication and a main mechanism for promoting this awareness

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<sup>63</sup> Not publicly available- copy on file with the author

<sup>64</sup> Ibid

<sup>65</sup> Ibid

<sup>66</sup> The second challenge for regulators is achieving regulatory effectiveness. See Chapter 3.2.2 of this thesis

<sup>67</sup> Section 33 of *RIHE Act 2002*

<sup>68</sup> Lockhart Report at 111. This model may raise the concern as to whether the inspectors may develop close relationships with the regulatees to undertake objective and rigorous oversight. However, applying Braithwaite's concept of tripartism, there should be more than one inspector conducting the audit and also there should be different inspectors conducting the audits at other times

is through information exchange visits. These visits are made to researchers, licence holders, human research ethics committee members and other interested organisations. In addition, information is made available through seminars, workshops, websites and publications. These strategies collectively comprise the ‘education’ rung of Braithwaite’s pyramid of regulatory strategies.

To assist new licence holders to meet the conditions of the licence relating to record keeping, an audit of the records is conducted within a few weeks after the issue of a licence.<sup>69</sup> At the time of licence expiry, a final inspection is conducted and the licence holder is advised by the inspector on the preparation of the final report on the licensed activities.

Licence holders may request advice from the inspectors either before or during an inspection.<sup>70</sup> Under the direction of the chair of the LC, inspectors may provide oral or written advice to bring issues as well as breaches to the attention of the licence holder.

Monitoring of activities include conducting inspections of premises, documents and records, and occurs at least annually for the duration of the licence.<sup>71</sup> Usually, visits are arranged in advance with the licence holder. Unannounced/ random inspections can occur but to date none have taken place. An inspector must produce an identity card on request<sup>72</sup> and entry must be at a reasonable time.<sup>73</sup>

Monitoring powers include searching the premises and anything on it,<sup>74</sup> inspecting any human embryos or thing on the premises that relates to the Act,<sup>75</sup> inspecting books, records, documents<sup>76</sup> and taking extracts from and making copies of them.<sup>77</sup> Monitoring powers also include the power to operate the equipment at premises to see whether the equipment or the disk, tape or other storage device contains

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<sup>69</sup> Lockhart Report at 111

<sup>70</sup> Ibid

<sup>71</sup> Ibid

<sup>72</sup> Section 38 of *RIHE Act 2002*

<sup>73</sup> Section 35(2)(b) of *RIHE Act 2002*

<sup>74</sup> Section 36(1)(a) of *RIHE Act 2002*

<sup>75</sup> Section 36(1)(b) of *RIHE Act 2002*

<sup>76</sup> Section 36(1)(d) of *RIHE Act 2002*

<sup>77</sup> Section 36(1)(e) of *RIHE Act 2002*

information that is relevant to determining whether there is compliance with the Act.<sup>78</sup> However, the LC has not required to use these provisions as inspections have been cooperatively arranged.

The inspector has power, pending the obtaining of warrant, to secure the human embryo or thing if, during a search of premises, he or she believes on reasonable grounds that the embryo or thing may be evidence of the commission of an offence.<sup>79</sup>

In the event of damage to the equipment or other facilities, the owner is entitled to compensation provided that the damage caused was a result of it being operated with insufficient care by the inspector.<sup>80</sup>

In the event of a serious case of noncompliance being detected during an inspection, or if a formal complaint is received by the LC, an investigation may be initiated,<sup>81</sup> including a referral of the breach to the Australian Federal Police for possible criminal prosecution. Again, the LC has only activated these provisions once.<sup>82</sup>

Monitoring by inspectors of activities undertaken by licence holders ensures regulatory effectiveness. The monitoring and compliance framework, based on a model of ‘cooperative compliance’, emphasises on education and communication to promote awareness of the responsibilities of both licence holders. The next section explains criminal offences as prescribed by *RIHE Act 2002*.

## 6.7 OFFENCES<sup>83</sup>

The *RIHE Act 2002* creates a number of criminal offences which carry a maximum penalty of five years imprisonment.<sup>84</sup> Offences under the *RIHE Act 2002* include:

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<sup>78</sup> Section 36(2) of *RIHE Act 2002*

<sup>79</sup> Section 37 of *RIHE Act 2002*

<sup>80</sup> Section 40(1) of *RIHE Act 2002*

<sup>81</sup> Lockhart Report at 111

<sup>82</sup> National Health Medical Research Council, *Report to the Parliament of Australia*, for the period 1 October 2004 to 31 March 2005 at 15

<sup>83</sup> The provisions on offences are found in Division 2 of the *RIHE Act 2002*

<sup>84</sup> Section 12 of *RIHE Act 2002*. At the discretion of the courts, the imprisonment may be supplemented by or converted to a monetary penalty of up to \$165,000 for a corporation or \$33,000 for an individual. See Explanatory Memorandum of *RIHE Act 2002* at 8

- Using excess ART embryo unless the use is authorised by a licence or is an exempt use;<sup>85</sup>
- Using of an embryo which is not an excess ART embryo;<sup>86</sup> and
- Breaching a licence condition.<sup>87</sup> ‘A person commits an offence if he or she intentionally engages in a conduct, knowing that the conduct contravenes a condition of a licence that applies to the person or recklessly to whether the conduct contravenes a condition of such a licence ... Engaging in conduct means (a) to do an act or (b) omit to perform an act.’

A non-compliance form is available online for anyone who wishes to lodge a formal complaint against person who is allegedly not complying with their responsibilities under the Acts.<sup>88</sup>

To date, there have been no prosecutions. However, there has been one investigation completed by NHMRC inspectors.<sup>89</sup> It was investigation of an alleged offence under ss9 and 10 of *PHC Act 2002*, that is, a claim that Clonaid<sup>90</sup> had created a human embryo clone and placed it into a human body.<sup>91</sup> According to the findings, the act occurred overseas, and so did not constitute an offence under the Act; the NHMRC inspectors are nonetheless maintaining a watching brief.<sup>92</sup>

## 6.8 COSTS OF LC AND A COST RECOVERY MECHANISM

The cost of supporting the LC is not insignificant, with a total commitment of \$3.3 million per year.<sup>93</sup> The costs include:

- A fixed amount to support the LC and to provide for ongoing compliance monitoring;

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<sup>85</sup> Section 10 of *RIHE Act 2002*. This section provides a long list of exempt uses which include storage, removal, transport of the embryo

<sup>86</sup> Section 11 of *RIHE Act 2002*

<sup>87</sup> Section 12 of *RIHE Act 2002*

<sup>88</sup> <http://www.nhmrc.gov.au/embryo/monitor/form/allegations.htm>

<sup>89</sup> See National Health Medical Research Council, *Report to the Parliament of Australia*, for the period 1 October 2004 to 31 March 2005 at 15

<sup>90</sup> Clonaid is a human cloning company with philosophical ties with the Raelian religion, which sees cloning as the first step in achieving immortality. See <http://www.clonaid.com/page.php?18?> (11 June 2010)

<sup>91</sup> *Report to the Parliament of Australia*, for the period 1 October 2004 to 31 March 2005 at 15

<sup>92</sup> Ibid

<sup>93</sup> This is provided by the Australian Government Portfolio Budget Statement at 99 of Lockhart Report

- A variable cost relating to the number of applications received; and
- The establishment costs including developing administrative processes for receiving and processing applications and issuing licences, recruiting skilled staff, establishing skilled inspectorate, assessment of research proposals and establishment and maintenance of data systems and public reporting.<sup>94</sup>

To date, no cost recovery mechanism has applied to recover these costs.<sup>95</sup> The Lockhart Report supports this viewpoint, explaining that because the number of licence applications received is small and

it is unlikely that introducing costs recovery would be cost-effective or efficient .... If total costs were to be recovered from licence holders, the cost would be exorbitant and would apply a strong disincentive to application, thus inhibiting the research that the system was established to enable.<sup>96</sup>

The Lockhart Report, in Recommendation 37 stated that there should be no attempt to recover the cost of administration, licensing, monitoring and inspections activities associated with the legislation from researchers at this point in time. This Recommendation was based partly on the view that applying a cost recovery mechanism may inhibit research.

## **6.9 IMPROVING THE EXISTING LICENSING SYSTEM**

Given that the Australian licensing scheme could provide a model for adoption in other jurisdictions, including Malaysia, it is necessary to critically analyse its strengths and weaknesses. The Lockhart committee accepted a number of suggestions to further improve the effectiveness of the existing licensing system.<sup>97</sup> The committee made a series of recommendations (Recommendations 34-39) with the aim of improving various aspects of the licensing system.

A number of submissions to the Lockhart review referred to the strengths and weaknesses of the licensing system, particularly a detailed submission from the

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<sup>94</sup> Explanatory Memorandum of *RIHE Act 2002* at 2

<sup>95</sup> The Productivity Commission has made some guidelines on when cost recovery should be implemented in their report, see 100 of Lockhart Report

<sup>96</sup> Lockhart Report at 100

<sup>97</sup> The critiques were mostly found in two chapters of the Lockhart Report; chapter 9 provided a critique on the licencing arrangements at 99-109 of the report and chapter 10 critiqued monitoring and compliance at 111-113 of the report



NHMRC.<sup>98</sup> The committee noted that respondents from all stakeholders groups were generally supportive of the need for strong oversight of this type of research, with several submissions acknowledging the professionalism of LC in issuing licenses for human embryos research using excess ART embryos.<sup>99</sup> The main benefits of the licensing process, as identified by Stem Cell Ethics Australia, included:

- General prohibitions, on grounds of safety or society attitudes, to be legislated;
- Uniformity across the Commonwealth and States;
- Appropriate and considered responsiveness to changes and developments in the science; and
- Some responsiveness to changes in community attitudes.<sup>100</sup>

There was also support for the licensing system from industry, particularly its role in the creation and maintenance of community trust in embryo research achieved through rigorous and transparent licensing requirements and processes. As submitted by Stem Cell Science Ltd:<sup>101</sup>

The stringent requirements imposed by the Licensing Committee to demonstrate ‘proper consent’ and ‘scientific merit’ of any proposed research project prior to the granting of a licence has reassured the Australian public that any research undertaken using human embryos is fully accountable and conducted in a conscientious manner.

In view of these favourable findings, the committee concluded that the LC generally fulfils a valuable role in this process and is broadly supported by researchers and the community. This was reflected in the following recommendations:

- Recommendation 34: the Licensing Committee should continue to be the regulatory body responsible for assessing licence applications, issuing licenses and monitoring compliance, as under current arrangements.
- Recommendation 35: the role of the Licensing Committee should be extended to include assessment of licensing applications and issuing

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<sup>98</sup> Submission LRC 790

<sup>99</sup> Lockhart Report at 103-104

<sup>100</sup> Ibid at 104

<sup>101</sup> Ibid

licences for any additional activities (which include SCNT) permitted under licence (Recommendations 14-27 lists the range of activities).

- Recommendation 38: the Licensing Committee should continue to perform its function in relation to license and databases for research permitted by licences under the RIHE Act.

However, the committee also acknowledged some criticisms of the LC, and some suggestions for improvement, which are explored below.

### **6.9.1 CRITICISM ONE: DELAYS IN APPLICATION PROCESS**

By far the most serious criticism of the licensing process is that it causes unnecessary delays in this rapidly moving area of research, potentially affecting the ability of Australian researchers to compete in the global race for research excellence. The inefficient and time-consuming nature of the application and review processes were major limitations of the licensing process. Lack of clarity in some aspects of the application process<sup>102</sup> and delays<sup>103</sup> (for instance, between the submission of the application and the grant of the approval) were also seen by researchers as inhibiting research.

The Fertility Society of Australia (in conjunction with Monash IVF) submitted:

Unfortunately, the lack of specificity relating to the processes caused the Licensing Committee many delays over the last 3 years. As a result, delays occurred within the research arena and applicants experienced a high level of confusion and frustration. Some groups within Australia chose to cease work in view of the difficulties associated with applying for a licence.<sup>104</sup>

At one of the hearings, Associate Professor Jeremy Thompson informed the committee that he had not applied for a licence because of restrictions and lack of support for training.<sup>105</sup> He branded the licensing process as too long, too constraining and too difficult, thus slowing research.<sup>106</sup> A similar view was expressed by Centenary Institute of Cancer Medicine and Cell Biology, where the

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<sup>102</sup> Lockhart Report at 108

<sup>103</sup> Ibid at 104-105

<sup>104</sup> Lockhart Report at 105

<sup>105</sup> Associate Professor Jeremy Thompson, Deputy Director of Research Centre for Reproductive Health, University of Adelaide at the Adelaide hearings at 105 of Lockhart Report

<sup>106</sup> Lockhart Report at 105

Head said that he had not applied for a licence and that the process inhibits research ‘by curbing inspiration and restricting academic freedom.’<sup>107</sup>

The committee noted that delays in issuing the first licences were an inevitable consequence of the process to establish new regulatory system in a complex area of legislation.<sup>108</sup> It acknowledged that most researchers understood that that system was new and that it would improve over time.<sup>109</sup> Some submissions recognised that the NHMRC required time to develop the best method of issuing and reviewing licences.<sup>110</sup> In its own submission, the LC noted a perception that the Committee was slow to make decisions, and some researchers were waiting for the reviews of the legislation to be completed.<sup>111</sup> This was, according to the report to some extent due to a lack public understanding of the licensing requirements, and the explanation given was as follows:

The LC issued the first licences 12 months after the Committee was appointed, that is 18 months after the legislation was passed. However, during that time, the LC has been required to concurrently receive applications for licences, develop policy and procedures to underpin the legislation, develop its relationship within the NHMRC structures and engage a community with a heightened expectation of what the implications of regulating embryo research would be ... When the LC was considering early licence applications and simultaneously developing policy and procedures, its activities were slowed by misunderstandings about the information required in applications. The LC engaged in extensive consultation and repeated rounds of question and answer in order to obtain the information it required to make a decision. Members of the LC and Secretariat also visited applicants to discuss the applications more efficient. These activities all contributed to the perception that the LC was slow to make decisions. However, it also demonstrated the LC’s willingness to communicate with applicants to help them improve their applications and its determination to observe all the requirements of the *RIHE Act*.<sup>112</sup>

The LC, in reaching decisions about licence applications, must balance two conflicting requirements in the *RIHE Act 2002*. The first is the need to restrict the number of excess ART embryos to that likely to be necessary to achieve the goals

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<sup>107</sup> This view was expressed by Professor John Rasko, the Group Head of the Gene and Stem Cell Therapy, Centenary Institute of Cancer Medicine and Cell Biology at the Sydney hearings at 105 of Lockhart Report

<sup>108</sup> Lockhart Report at 100

<sup>109</sup> This was the view of Dr Kuldip Sidhu, Chief Hospital Scientist, Diabetes Transplant Unit, Prince of Wales Hospital at 104 of Lockhart report

<sup>110</sup> Lockhart Report at 105

<sup>111</sup> Ibid at 101

<sup>112</sup> Lockhart Report at 100

of the research project; the second is to consider the need to take into account the likelihood of significant advance in knowledge or improvement in technologies for treatment as the result of use of the excess embryos. There is an obvious tension which might slow down the application process.<sup>113</sup> The tension is inevitable because, on one hand, there is a need to limit the number of embryos to address public concerns as every embryo is important and, on the other hand, there is a need to have a certain number of embryos to achieve some success in the research and such science tension is not unique to embryo research. As explained by the LC:

... the best experiment is not necessarily the one which uses the fewest embryos or eggs in an absolute sense. Rather, it is the experiment which is designed to give the most reliable answer to the question being asked and, in most cases, which permits a statistically significant outcome. Poor experimental design can lead to the use of more eggs or embryos than absolutely necessary because the results may be ambiguous or unreliable. In this situation, the work would have to be repeated, thus potentially using more eggs or embryos in total than a few more had been used initially for a single experiment.<sup>114</sup>

In a public hearing, it was suggested that the time frame for the application process should be between three to six months.<sup>115</sup> The NHMRC has suggested that amendments be made to the legislation in order to improve the efficiency and clarity of the application process.<sup>116</sup>

The committee did not make specific recommendations to improve the efficiency of the application process, so none were included in the *Amendment Act 2006*. As the committee noted, the delays in issuing the initial licences were unavoidable in the establishment of a new regulatory system in a complex area of legislation<sup>117</sup> and over time, the efficiency would improve.<sup>118</sup> It will be revealing to see whether the system has improved since the Lockhart Report when the legislation review is again established.

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<sup>113</sup> NHMRC submission to the Legislation Review Committee at 39

<sup>114</sup> At A3:8 of Information Kit

<sup>115</sup> This suggestion was put forward in a public hearing in Sydney by Dr Kuldip Sidhu, Chief Hospital Scientist, Diabetes Transplant Unit, Prince of Wales Hospital at 104 of Lockhart Report

<sup>116</sup> Lockhart Report at 177

<sup>117</sup> Ibid at 100

<sup>118</sup> Ibid at 104

### 6.9.2 CRITICISM TWO: CHALLENGES ENCOUNTERED BY HUMAN RESEARCH ETHICS COMMITTEE

As explained in section 6.5, at the first stage of licence application applicants must present their proposal to HREC in their institution, and the HREC must be satisfied that the embryos are excess to the need of the couple in the ART programme and all necessary consents have been obtained. When the HREC approves the proposal, the application can be referred to the LC for consideration. The LC must issue licences only if satisfied that the proposed activity has been considered and approved by an HREC acting in compliance with the *National Statement on Ethical Conduct in Human Research*.

However, the LC noted in its submission to the Lockhart review that HRECS had encountered some difficulties in understanding and performing their role with respect to consideration of licence applications.<sup>119</sup> Similar comments were raised by AHEC in the same submission. It submitted:

the difficulties arise because both HREC ... and LC must consider the question of the likelihood of significant advance in knowledge and improvement in technology ... difficulties arise if HREC decides not to approve a project because it does not promise significant advance in knowledge ... this appears to subvert the apparent intention of the Act that this matter is one on which the LC ought to make the final determination.<sup>120</sup>

AHEC suggested that the legislation be amended to require that the LC to have regard to the advice of the HREC rather than making HREC's approval a condition precedent to the grant of a licence.<sup>121</sup>

The committee made no recommendation to amend the legislation in this manner, and therefore the *Amendment Act 2006* did not address the point. The committee considered that this 'practical issue could be managed under s15 *RIHE Act 2002*, which provides that the LC 'has power to do all things necessary or convenient to

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<sup>119</sup> Ibid at 103

<sup>120</sup> Lockhart Report at 103

<sup>121</sup> Ibid. Section 21(3)(c) of *RIHE Act 2002* provides that before issuing a licence, the LC must be satisfied that the proposed activity has been considered and approved by an HREC

be done for or in connection with the performance of its functions.’<sup>122</sup> The LC has been working with HRECs to address these difficulties.<sup>123</sup>

### **6.9.3 CRITICISM THREE: WHERE A SINGLE LICENCE IS ISSUED TO TWO COLLABORATING ORGANISATIONS**

Where two collaborating organisations submit a licence application and a licence is issued only to a single organisation, that is, to the organisation on whose premises the embryo will be destroyed, the subsequent work on the cells isolated from the embryos at the collaborating organisation is therefore outside the oversight of the LC.<sup>124</sup> This was identified by the LC as a problem, first with respect to assessing the potential for ‘significant advance’, and second, for monitoring and compliance. The LC explained:

Because regulatory control relates to the use of the embryo (and not to steps that occur after the embryo has been used), the LC has had to put in place sometimes complex administrative arrangements to ensure appropriate oversight of work being undertaken across different organisations. This has been evident with some of the licences involving the development of embryonic stem cell lines, where the use of the embryos and initial isolation of stem cells occurs in one organisation and development of the cell lines occurs in a second organisation. One avenue to address this is to provide or the capacity to have joint licence applications and holders, to confer the obligations for the provisions of information and reporting on all organisations involved.<sup>125</sup>

The LC proposed a provision in the Act for licences to be held jointly by two organisations would overcome this difficulty.<sup>126</sup> However, the committee made no recommendation so, again the *Amendment Act 2006* did not address the point. The committee considered the issuing of a licence jointly held by two organisations ‘was a matter for the LC to decide, with legal advice, if necessary.’<sup>127</sup>

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<sup>122</sup> Lockhart Report at 177

<sup>123</sup> Ibid at 103

<sup>124</sup> Ibid at 102

<sup>125</sup> Lockhart Report at 102

<sup>126</sup> Ibid

<sup>127</sup> Ibid at 177

#### **6.9.4 CRITICISM FOUR: DIFFICULTIES IN INTERPRETING *RIHE ACT 2002***

There have been difficulties in interpreting the meaning of some sections of the *RIHE Act 2002* on licensing. First, licence holders have raised the question whether thawing of an embryo should be considered as part of licence activity under s10 of the *RIHE Act 2002*.<sup>128</sup> This question is important because s10 may be interpreted to mean that only people who are authorised by the licence are allowed to thaw the embryos before their use in a licensed activity. The LC proposed that s10 be amended to remove the ambiguity.

Secondly, the Act does not specify the status of embryos which are not used. These embryos cannot simply be transferred for another project without getting new consent from the responsible persons. The LC has developed a standard condition to cover this situation by requesting the licence holder to transfer the embryos back to the ART clinics they come from or if they are also the ART clinic, to ask the responsible persons for new consent.<sup>129</sup> However, LC raised the question whether this uncertainty should be dealt with by the Act rather than by administrative process such as a licence condition.<sup>130</sup>

The committee made no recommendation on these two ambiguities and the *Amendment Act 2006* did not deal with them. Again, the committee considered that these matters could be dealt with under s15 of *RIHE Act 2002*.<sup>131</sup>

#### **6.9.5 CRITICISM FIVE: LACK OF POWERS TO SUSPEND OR REVOKE LICENCES IN CERTAIN CIRCUMSTANCES**

The LC claimed that it lack powers to suspend or revoke licences under the *RIHE Act 2002* as it is only able to do so if there are reasonable grounds to believe that there has been a breach of condition.<sup>132</sup> The LC therefore proposed to have the power to reconsider its decision to issue a licence in circumstances, for example,

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<sup>128</sup> Ibid at 102

<sup>129</sup> Ibid

<sup>130</sup> Lockhart Report at 102

<sup>131</sup> Ibid at 177

<sup>132</sup> Ibid at 103

where after becoming aware that a licence was issued on the basis of inadequate, incorrect or fraudulent information provided by the applicant.

The committee made no recommendation on this point, and again, considered that s15 of *RIHE Act 2002* provided the LC with the ‘power ... necessary or convenient ...’ to suspend or revoke licences in appropriate circumstances.<sup>133</sup>

#### **6.9.6 CRITICISM SIX: NO FEEDBACK OF RESEARCH OUTCOMES FROM RESEARCHERS**

The LC claimed that its regulatory role was restricted to oversight of the use of the embryo with no ability to oversee the steps that occur after the embryo had been destroyed by removal of the inner cell mass.<sup>134</sup> This limitation made it difficult for the LC to evaluate whether a licence achieved its stated goals and, which restricted the LC’s ability to take into account the likelihood of significant advance arising from the licence application. The LC raised the concern for the need to receive feedback of research outcomes from researchers. This is to inform further decisions relating to whether such research represents a ‘significant advance in knowledge or improvement in technology’. The LC recommended that it should have the power to require mandatory reports from researchers using HESCs derived from licence activities, and for a reasonable period beyond the conclusion of the licence as a condition of the issuing of a licence.<sup>135</sup>

The committee did not put forward any recommendation. The reason was that the committee agreed with the LC’s recommendation that it should require report from researchers using HESC derived from licensed activities and for a reasonable period beyond the conclusion of the licence, as a condition of the issuing of a licence, similar to reporting to HREC as a condition of the licence under s24 of *RIHE Act 2002*.<sup>136</sup>

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<sup>133</sup> Ibid at 177

<sup>134</sup> Ibid at 102

<sup>135</sup> Lockhart Report at 102

<sup>136</sup> Ibid at 177



### 6.9.7 CRITICISM SEVEN: LIMITED MONITORING POWERS OF THE LICENSING COMMITTEE

As discussed at 6.6, monitoring by inspectors of activities undertaken by licence holders is recognised as crucial to fulfil the requirement of regulatory effectiveness as formulated by Brownsword.<sup>137</sup> Two concerns were raised in the Lockhart Report related to the LC's monitoring powers.

First, a serious cause for concern was the inspectors' limited powers to monitoring activities that were not covered by a licence, where activities occurred in non-licensed premises. In a submission, it provided:

Currently, the LC has responsibility for monitoring compliance with the PHCA but its powers are limited if the organisation is not a licence holder. That is, NHMRC inspectors have the power to enter and inspect the premises of licence holders, but if the organisation is not licensed, then entry and inspection can only be undertaken with consent from the occupiers of the premises.<sup>138</sup>

Therefore, suspected breaches by non-licence-holders cannot be adequately investigated. In such event, inspectors need to refer the investigation to the Australian Federal Police for the issuing of a search warrant. Inspectors have established arrangements with the Australian Federal Police and relevant State and Territory agencies. However, the matter would have to be referred to the Australian Federal Police only on the basis of a belief, rather than suspicion, that a breach had occurred. Hence, the only way for the inspectors to become aware of a possible breach is if the breach was reported to the LC. In contrast, the *Gene Technology Act 2000* (Cth) allows inspectors to obtain a warrant from a magistrate on the basis of suspicion that a breach has occurred or is about to occur. The committee's view was that inspectors should have adequate powers under the Act to investigate suspected breaches of the *RIHE Act 2002* by non-licence holders.<sup>139</sup>

The second concern raised in the report was that inspectors lacked the power to make unannounced inspections in licensed premises.<sup>140</sup> This too inhibited their

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<sup>137</sup> The second challenge for regulators is achieving regulatory effectiveness. See Chapter 3.2.2 of this thesis

<sup>138</sup> Lockhart Report at 112

<sup>139</sup> Lockhart Report at 112

<sup>140</sup> Ibid at 113

ability to investigate suspected breaches. It suggested regular and random inspections to ensure that prohibited practices are not being carried out:

Inspectors ought to conduct regular random inspections to ensure that prohibited practices are not being carried out. It is not apparent that this is happening at the present time, nor that there is a proactive approach to investigation in respect of prohibited practices. The results of those inspections ought to be publicly available in some suitable form.<sup>141</sup>

The report, in Recommendation 39, provided that the LC inspectors should be given powers under the Act of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants. This recommendation was reflected in section 37 of the *Amendment Act 2006* which provides for these additional powers to inspectors for monitoring compliance in relation to non-licensed facilities under search warrants.<sup>142</sup> An inspector may apply to a magistrate for a warrant. The warrant may be issued if the magistrate is satisfied by the information provided by the inspectors that it is reasonably necessary that they have access to the premises for the purposes of determining whether the Act has been complied with.<sup>143</sup> Other subsections of the Act provide for matters like details of warrant to be given to occupier,<sup>144</sup> announcement before entry<sup>145</sup> and the entitlement of the occupier to be present during search.<sup>146</sup> This approach is consistent with the approach in the *Gene Technology Act 2002* as well as with general Australian Government law enforcement policy.<sup>147</sup>

#### **6.9.8 CRITICISM EIGHT: LACK OF DELEGATION OF DUTIES**

The LC noted that the *RIHE Act 2002* does not empower the LC to delegate a decision to the Chair, which in turn limits its ability to act promptly when an urgent decision is required.<sup>148</sup> Similarly, the Act also makes no provisions for the Chair to delegate functions or powers to a Deputy Chair. The NHMRC recommended that the *RIHE Act 2002* be amended to permit such delegations of duties. The committee

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<sup>141</sup> Ibid

<sup>142</sup> Explanatory Memorandum of the *Amendment Bill 2006* at 33-34. Section 35(2)(c) and section 36(1)(g) are inserted

<sup>143</sup> Section 37A of *RIHE Act 2002*

<sup>144</sup> Section 37B of *RIHE Act 2002*

<sup>145</sup> Section 37C of *RIHE Act 2002*

<sup>146</sup> Section 37D of *RIHE Act 2002*

<sup>147</sup> Explanatory Memorandum of the *Amendment Bill 2006* at 33-34

<sup>148</sup> Lockhart Report at 103

made no recommendation on a Deputy Chair and considered that this was another matter to be dealt with under s15 of *RIHE Act 2002*.<sup>149</sup>

#### **6.9.9 CRITICISM NINE: VACANCIES IN THE LICENSING COMMITTEE**

The committee heard that a vacancy, due to resignation or death of a member of the LC, poses a significant problem as licensing applications cannot be handled effectively. This is due to the specific expertise of each LC member.<sup>150</sup> There have been lengthy delays in filling vacancies since appointment to the committee involves approval by all States and Territories. The Lockhart Committee saw no scope in the Act to address this problem, as the LC is a national committee that oversees research in all States and Territories, and it drew this urgent concern to the attention of the Australian Parliament and the Council of Australian Governments for consideration.

The committee put forward Recommendation 36 which provided that the Australian Parliament and the Council of Australian Government should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee. This recommendation was reflected in s16 of the *Amendment Act 2006*, which provided that it is the intention of the Parliament that any vacancy on the LC be filled as soon as possible<sup>151</sup> and if there is a vacancy for a period of three months, the Minister must within three sitting days of the expiration of the three months, table in each House of Parliament a written statement of reasons of the failure to fill the vacancy.<sup>152</sup>

### **6.10 CONCLUSION**

This chapter provides evidence that the Australian regulatory model on research involving human embryos achieves regulatory effectiveness through its statutory licensing system. It illustrates the important role the LC has played in the strict control of the research and also the crucial function of inspectors in strictly monitoring licensed holders' compliance with the legislation.

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<sup>149</sup> Ibid at 177

<sup>150</sup> Ibid

<sup>151</sup> Section 16(7) of *RIHE Act 2002*

<sup>152</sup> Section 16(8) of *RIHE Act 2002*

The LC has played a major role in the effective regulation of research involving human embryos in Australia since 2003, and continued after the *Amendment Act 2006* was passed. There is general support for the need of oversight of embryo and stem cell research, and the LC fulfils a valuable role in this process based on submissions in the Lockhart review. These favourable submissions influenced Recommendations 34, 35 and 38, which provided for the continuity of the LC as the regulatory body in this area of enforcement.

An important issue this chapter illustrates is a striking feature of the Australian regulatory regime on stem cell research, that is, is the application of Braithwaite's theory of regulation. Its regulatory framework illustrates three rungs of the pyramid of regulatory strategies incorporating a mix of different approaches namely, education, followed by National Guidelines and at the apex, strict statutory licensing system. As supported by Brownsword, a collective mix of regulatory strategies ensures regulatory effectiveness.<sup>153</sup> At the lowest rung in Braithwaite's regulatory pyramid, education visits to research centres by the LC and auditors create awareness among researchers of their responsibilities under the Acts. On the next rung of the pyramid are the national guidelines which must be complied with by the applicant of the licence (there is strict criteria which the LC must adhere to before issuing licenses, that is, only where it is satisfied that the proposed activity has been considered and approved by an HREC acting in compliance with the NHMRC's *National Statement 2007*<sup>154</sup> and the LC must have regard to whether other relevant guidelines issued by the NHMRC have been followed<sup>155</sup>). Finally, at the apex of the pyramid are the statutory provisions of *RIHE Act 2002* that set up the licensing system.

There have been no prosecutions to date and this may be an indicator of the success of the Australian regulatory model. As Brownsword explains, regulators achieve regulatory effectiveness when their intervention works. It is therefore acknowledged that the evolving responsive Australian regulatory regime, incorporating a mix of statutory licensing system, adherence to NHMRC guidelines

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<sup>153</sup> See Chapter 3.2.2

<sup>154</sup> Section 21(3)(c) of *RIHE Act 2002*

<sup>155</sup> Section 21(4)(c) of *RIHE Act 2002*

and education promoting awareness of responsibilities, backed by monitoring and inspection system for facilitating monitoring compliance with the legislation, achieves regulatory effectiveness.

The other striking feature which this chapter demonstrates is that the Australian regulatory framework maintains regulatory connection as illustrated by the changes made to the LC and its operations based on the recommendations put forward in the Lockhart review.

In summary, the Australian regulatory framework governing embryo research achieves regulatory legitimacy, attains regulatory effectiveness and maintains regulatory connection, thus fulfilling Brownsword's template of effective regulation of modern technologies. In addition, it also meets Braithwaite's pyramid test of responsive regulation.

These important features of the Australian regulatory model analysed in Part 2 of this thesis are useful references for the Malaysian government in setting up an effective regulatory framework to govern HESC research in the country. In the next section, Part 3 of the thesis, Malaysia's existing regulatory model on HESC research is critically assessed and this is followed by some recommendations.

### **PART 3: THE REGULATORY REGIME FOR USE OF HUMAN EMBRYOS IN RESEARCH IN MALAYSIA**

The Malaysian government has identified biotechnology, which includes stem cell research, as one of the core technologies to facilitate the transformation from developing country into a fully industrialised nation. The regulation on stem cell research is in the form of guidelines, the *Malaysian Guidelines for Stem Cell Research and Therapy 2009* (the *Guidelines 2009*) and the essential issue to examine is whether it is necessary for the Malaysian government to consider moving to the next level, that is, to adopt a regulatory framework, which includes comprehensive legislation, to govern HESC research.

In this Part 3 of the thesis, Chapter 7 explores the challenge of achieving regulatory legitimacy in this multi-religious nation and Chapter 8 critically assesses the *Guidelines 2009*. The conclusion is found in Chapter 9 which unveils a responsive regulatory regime for use of human embryos in research in Malaysia.

## 7: THE CHALLENGE OF REGULATORY LEGITIMACY

### 7.1 INTRODUCTION

Religious views have been prominent in debates and reports on cloning and stem cell research.<sup>1</sup> They are informed by ethical, theological and legal issues. The debate on the moral status of the human embryo, discussed in the Chapter 1, is closely linked to philosophical and religious perspectives on the subject of human embryonic stem cell (HESC) research.

The majority of Malaysia's population are Muslims, but there are also large numbers of Buddhists, Christians, Hindus and Sikhs.<sup>2</sup> Islam is the official religion in the nation as provided in Article 3, *Federal Constitution of Malaysia* which reads:

3(1) Islam is the religion of the Federation; but other religions may be practiced in peace and harmony in any part of the Federation.

However, it is debatable and unclear whether the nation is an Islamic state or a secular state.<sup>3</sup>

This chapter explores and compares the various religious perspectives of the main religions in Malaysia on HESC research and notes the following challenges. First, HESC research raises issues of deep religious significance. Secondly, within Malaysian society, there is religious diversity. Thirdly, this problem is accentuated by the fact there is no single authoritative voice that speaks for the religion as this involves making interpretations of holy texts that may lead to conflicting ones. Fourthly, scientific advances have reached a stage where much modern biomedical research is new both theoretically and in practice, unimaginable when the ancient

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<sup>1</sup> See for instance, House of Representatives Standing Committee of Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001) Canberra (Andrews Report)

<sup>2</sup> According to the Department of Statistics Malaysia, the demographics of the Malaysian population are 60.4% Muslims, 19.2% Buddhists, 9.1% Christians, 6.3% Hindus and others which include Sikhs. See <http://www.statistics.gov.my/portal/index.php?lang=en> (13 May 2010)

<sup>3</sup> This has been a sensitive discussion in the country in recent years

sacred texts were written. With the emergence of modern developments like HESC research, new orientations to theological/ religious texts are required.

This chapter explores the discussions and interpretations of the main religions of Malaysia: Islam, Catholicism, Buddhism, Hinduism and Sikhism. During the course of this thesis, interviews were conducted with representatives of each of these religions. These included religious leaders, religious scholars, pastor, priests and monks. These interviews confirmed that there is less controversy about embryo experimentation and stem cell research in Malaysia than Australia. Religious views have been less prominent in debates in Malaysia and this may, in large measure be explained by the *Fatwa* on therapeutic cloning and stem cell research that was issued in 2005. The interviewees expressed their views with references to sacred texts that embody the wisdom of their religion.<sup>4</sup> As this is a legal thesis and not on philosophy/ religion, it is beyond the scope of this chapter to discuss in extensive detail the various philosophical foundations for each of the five religions.

## **7.2 THE ISLAMIC PERSPECTIVE**

### **7.2.1 BASIC PHILOSOPHY**

Islam is a monotheistic religion with a belief in one God. Its teachings provide a complete and comprehensive way of life,<sup>5</sup> encompassing ‘all fields of human endeavours, spiritual and material, individual and societal, economics and politics, national and international.’<sup>6</sup> The instructions regulating a Muslim’s daily activities, *shariah*/ Islamic law/ jurisprudence, apply to all Muslims, everywhere and at all times. As bioethical deliberations are inseparable from religion, Islamic bioethics is decided in accordance with *shariah*. As a dynamic and relevant entity, it also applies to contemporary emerging biotechnologies including HESC research.

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<sup>4</sup> See 7.7 of this chapter on the findings of the interviews

<sup>5</sup> Face-to-face interview with Dr Musa bin Nordin, President of the Federation of Islam Medical Association in Malaysia, 7 January 2008, interview by Chee Kuen Foong (Patrick)

<sup>6</sup> Nordin M, ‘Islamic Medical Ethics amidst Developing Biotechnologies’ <http://www.fimaweb.net/main/medicalethics/islamicmedicalethicsamidstdevelopingbiotechnologies.doc> (2 August 2007)



Islamic scholars believe that knowledge emanates from God and, as such, human beings have an obligation to use the knowledge to serve society.<sup>7</sup> Its followers have obligations to seek knowledge, in particular scientific knowledge. The Muslim world attempts to keep at the cutting edge of science. The first verse of the Quran to Prophet Mohammad was:

Read! In the name of your Lord, who has created. Has created man from alaqah.<sup>8</sup>

### 7.2.2 MORAL STATUS OF HUMAN EMBRYO

For centuries, Muslim scholars have discussed issues of *ruh*/ soul. In the past four decades, this issue has been addressed in the context of increasingly successive scientific developments and advances in biomedical topics including birth control, abortion, in-vitro fertilisation (IVF), research on embryos, embryo banking, stem cell research and genetic engineering. The Quran, which was revealed by Allah to Prophet Mohammad, is the primary source of teachings for Muslims. The Hadith, which contains the sayings of Prophet Muhammad, is the second most important source of teachings.<sup>9</sup>

Like Catholicism and Judaism, Islam recognises the concept of ensoulment and the status of personhood. Ensoulment refers to the moment at which a human embryo receives the soul and thereby gains its moral status and rights as a legal person. Islam acknowledges dualism, that is, body and soul subsist together and meet to form a complete person.

In both Quran and Hadith, references are made to the *ruh*. References found in the Quran include:

He created all things in the best way and He began the creation of man from clay. Then made his progeny from a quintessence of despised liquid. Then He created him in due proportion and breathed into him of His spirit. And He gave you the faculties of hearing and sight and hearts. Little thanks do ye give!<sup>10</sup>

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<sup>7</sup> In an interview with Dr Musa, 7 January 2008, Petaling Jaya

<sup>8</sup> 96:1-2 of Quran

<sup>9</sup> The Hadith is also known as Ahadith

<sup>10</sup> 32: 8-9 of Quran

This verse explains that first, the human is shaped in due proportion, then he/ she is ensouled and, finally, the faculties of hearing and sight and heart are formed. It explains that ensoulment occurs during the intrauterine life.

Also in the Quran, other verses provide:

And indeed We created man from a quintessence of clay. Then We placed him as a small quantity of liquid (nufta) in a safe lodging firmly established. Then We have fashioned the nufta into something which clings (alaqa) then We made alaqa into a chewed lump of flesh (mudgha) and We made out of that chewed lump of flesh into bones and clothed the bones with flesh. And then We brought it forth as another creation. So blessed be God, the Best to create!<sup>11</sup>

This passage has been interpreted to mean that an embryo is perceived as a human life only later on in the biological development because of the use of the words ‘thereafter we produced him as another creature.’

In the Hadith, there are some verses which are interpreted that human life begins at the moment of ensoulment which is on 120<sup>th</sup> day after conception, equivalent to 134 days after the last menstrual period (lmp) used by obstetricians. It says:

Each one of you is put together in his mother’s womb in forty days, then he becomes a hanging clot in a similar time, then he becomes a mass of flesh in a similar time, then Allah send an angel who is ordered to establish four issues: his sustenance, his destiny, his deeds and whether he will be mischievous or happy, then He breathes the soul unto him.<sup>12</sup>

Another verse in the Hadith says:

After the zygote (nufta) has been established in the womb for forty or forty five nights, the angel comes and says “My Lord, will he be wretched or fortunate?” And both these things are written. Then the angel says: “My Lord, would he be male or female?” And both these things are written. And his deeds and actions, his death, his livelihood; these are also recorded. Then his document of destiny is rolled and there is no addition to and subtraction from it.<sup>13</sup>

As early as the 14<sup>th</sup> century, Muslim scholars had discussed the concept of ensoulment. Ibnul Al Qayim asked:

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<sup>11</sup> 23: 12-14 of Quran

<sup>12</sup> Sahih al-Bukahri 1/10

<sup>13</sup> Narrated by Huzaifah Ibn Aseed

Does the embryo, before the breathing of the soul unto it, have perception and movement? It is answered that the movement it possess is like that of a growing plant. Its movements and perception are not voluntary. When the soul is breathed unto the body, the movements and perceptions become voluntary and are added to the vegetative type of life it had prior to the breathing of the soul. It has the life of growth and nourishment like a plant. Once the soul enters the body, then it has the sense of perception and volition, which constitute the basis of human life.<sup>14</sup>

Another scholar, Ibn Hajar Al Asqalani, argued that the liver is the first organ formed in the embryo as it is important for growth and nourishment.<sup>15</sup> He explained that the formation of the brain comes at a later stage when the soul enters the foetus. He linked the soul by the appearance of voluntary movements in the foetus.<sup>16</sup> Islamic religious thinkers link ensoulment to the formation and integration of the nervous system, where the centres of perception and volition are found.

However, among Muslim religious scholars, there is a debate as to the precise moment of ensoulment. Until recently, the unanimous accepted view is ensoulment occurs after four months/ 120 days from conception and this view has become well established. However, in recent times, contemporary religious scholars have argued that there is evidence in both Quran and Hadith that speak differently, that is, ensoulment occurs after 40 days from conception.<sup>17</sup> This interpretation is supported in these verses of the Quran which provide:

We created man from the finest extract of clay. Then We placed him as a drop of semen in a firm lodging. Then We fashioned the drop into a hanging clot. Then We fashioned the clot into a lump of flesh. Then from the lump of flesh We fashioned bones, then covered bones with flesh. Then We formed him into a new creation ...<sup>18</sup>

The verses have been interpreted to represent seven stages of fetal development. Each stage is explained as follows:

- The first stage is the creation of clay. This implies the creation of Adam from clay, soil and water. Sperm and egg originate from human bodies which are built from nutrients that originate from clay.

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<sup>14</sup> Ibnul Al Qayyim, *Altibian Fi Aqsam Al Quraan* at 255 (available only in Arabic)

<sup>15</sup> Ibn Hajar Al Asqalani, *Fathel Bari-Ketabul Qadar* at 48 (available only in Arabic)

<sup>16</sup> Ibid

<sup>17</sup> Mishal A, 'Human Life before Birth: The Contemporary Issues' (2002) *FIMA Year Book* 1-13

<sup>18</sup> 12-14 of Quran

- The second stage is the drop of sperm-egg.
- The third stage is the hanging clot. This forms around the seventh day from fertilisation. The hanging clot is attached to the endometrium by fine villi. It looks like an object hanging to the endometrium.
- The fourth stage is the development of flesh mass or mass of somites. This stage starts at the end of the third week or the beginning of the fourth.
- The fifth stage is the bone development. Early stages of bone development start in the sixth week.
- The sixth stage is the muscle development. Several days after, muscle development start at the sixth week.
- The seventh stage 'Then We formed him into a new creation' denotes the beginning of *ruh* around the seventh week.

Some scholars interpret similar time to mean time equals to this period rather than in the same period.

There are other passages in Hadith that suggest that ensoulment takes place on the 40<sup>th</sup> day after conception:

- Each one of you I put together in his mother's womb in forty days then, and during the same time, he becomes a hanging clot, then, and during the same time, he becomes a mass of flesh, then Allah sends the angel who is ordered breath *ruh* into it, and to down four issues ...<sup>19</sup>
- The angel enters to the semen drop, forty days or forty nights after it settles in the womb. The angel says: O Allah, is he mischievous or happy? And the angel writes down. Then the angel says: O Allah is he male or female? And he writes. He also writes his deeds, destiny and sustenance. Then the papers are folded (record closed) with no addition or omission in them.<sup>20</sup>
- When the forty two nights have passed over the drop of semen (in the womb), Allah sends an angel who pictures it and witnesses the creation of its hearing, vision, skin, flesh and bone, then the angel asks: O Allah

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<sup>19</sup> Sahih Muslim 4/2064

<sup>20</sup> This passage and the next three passages were narrated by Huthaifah Ibn Usaid

is it male of female, and Allah decides what He wishes, the angel writes. Then the angel asks: O Allah, his destiny? Allah decides what He wishes and the angel writes. The angel then asks: O Allah, his sustenance? Allah decides what he wishes and he angel writes. Then the angel emerges out with the paper in his hand, after which no addition or omissions takes place to what he was ordered to write.

- The drop of semen settles for forty nights in the womb, then the angel is sent to it ...
- An angel is assigned to the womb when Allah wishes to create something in it after some and forty nights ...

From these Hadith passages, it can be interpreted that the *ruh* is breathed into the embryo after the first 40 days from conception. Contemporary scholars understand the concept that combines the three stages of a fertilised egg, hanging cot and somatic mass to take effect on set of 40 days rather than a succession of three sets of consecutive 40 days. In the first saying, it states that the writing of destiny occurs at the same time as the breathing of the *ruh*.<sup>21</sup> The last five sayings, however, do not mention the breathing of the *ruh* but they refer to the fashioning of the creation and writing destiny of the foetus.

While it is debateable whether ensoulment occurs on 40th day or 120th day after conception, the interpretation is liberal in comparison to other religions. Catholicism, for example, teaches that it occurs at the time of conception.<sup>22</sup> Accordingly, it can be argued that in research involving human embryos, the destruction of the human embryo which occurs on the fifth day after fertilisation does not violate Islamic law. Similarly, with early termination of pregnancy, it is argued that abortion is not murder since the embryo is not yet a person at that time.<sup>23</sup> The *Shariah* makes a distinction between potential life and actual life, determining that actual life should be afforded more protection than potential life.

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<sup>21</sup> See Mishal A, 'Human Life before Birth: The Contemporary Issues' at 5

<sup>22</sup> See 7.3.2 of this chapter

<sup>23</sup> The official *Fatwa* is that abortion is permitted in the first 40 days of conception. However, in 1990 Islamic World League held in Makkah, this was extended to 120 days after conception. Many Islamic jurists are more stringent and would allow abortion only in the first 40 days of conception. Some jurists will not allow abortion at any time of pregnancy except to save the life of the mother

Under most interpretations of Islamic law, the human embryo is not considered as a person and the use of it for stem cell research does not violate Islamic law. Under the same line of analysis, stem cells from aborted fetuses would also be permitted if the abortion was performed before the fourth month of pregnancy. HESC research might be regarded as an act of faith in the ultimate will of Allah as the giver of all life, as long as the intervention is undertaken with the purpose of improving human health.

However, it is noted that prior to ensoulment, the embryo has sanctity but not reaching that of a full human being. A Muslim scholar, Abu Hamid al-Ghazali,<sup>24</sup> stated that the embryo should be respected from the moment of fertilisation. Although ensoulment occurs at a later stage, there should be no disregard for the sacredness of the human embryo. From the moment of conception, the early embryo is a unique developing living creature being prepared by God to receive a soul.<sup>25</sup> Therefore, in Islam, human life in all its stages, is glorified and honoured despite ensoulment, which is interpreted to occur whether on 40<sup>th</sup> or 120<sup>th</sup> day after conception.

The majority of the Islamic religious scholars approve of the use of excess ART embryos in research since these embryos will be discarded any way. However, the use of cloned embryos using SCNT technology is not permitted since it involves the deliberate creation of embryos.

### **7.2.3 ISLAMIC LEGAL RESOLUTIONS, *FATWAS***

Unlike the Vatican in the Catholic religion, Islam does not have a centralised authority to state an official position on the moral status of human embryos and issues surrounding HESC research. In Islam, there are *Fatwas*, legal opinion issued by a *mufti*/ expert, demonstrating a ruling within Islamic law based on evidence as a response to question.<sup>26</sup> *Fatwas* are not legally binding and they can be revised as science progresses. In Malaysia, *Fatwas* are issued by the National Fatwa

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<sup>24</sup> Abu Hamid al-Ghazali *Ihya' Ulumeddin* at 65. Abu was one of the great Muslim jurists, theologians and mystics of the 12th Century. He wrote on a wide range of topics including jurisprudence, theology, mysticism and philosophy

<sup>25</sup> In an interview with Dr Musa, 7 January 2008, Petaling Jaya

<sup>26</sup> A *Fatwa* may concern any aspects of an individual's life including marriage issues, financial affairs and moral questions

Committee.<sup>27</sup> In 2005 the *Fatwa* on therapeutic cloning and stem cell research was issued. The *Fatwa* has been influential in the drafting of Malaysia's National Guidelines on Stem Cell Research.<sup>28</sup> At the international level, the Islamic Fiqh Academy issues *Fatwas* but these are not binding on Islamic states.

#### 7.2.4 INTERNATIONAL ISLAMIC CONFERENCES

In 1983 a convention entitled 'Procreation in Islam' was held where two papers were presented dealing with the possibility of human cloning as a result of successful cloning in plants, frogs and small marine animals.<sup>29</sup> At the conclusion of the convention, a recommendation was made:

To exercise prudence in giving a *shariah* based opinion on human cloning and to call for further medical and Islamic investigation of these issues.

Subsequent to the creation of Dolly in 1997, in every Islamic conference/ seminar, reproductive cloning was proclaimed to be prohibited.<sup>30</sup> In 1997 the Islamic Fiqh Academy issued a *Fatwa* stating that human cloning is haram/ prohibited.<sup>31</sup> A majority of Islamic scholars consider the activity *haram* for the following reasons:<sup>32</sup>

- The basic concept in reproduction is to abide by *Shariah*'s approved system of a marriage, that is, through the union of sperm and egg;
- Reproductive cloning is against the natural process, *fitrah*, of human relationship of marriage and reproduction;
- The harms exceed the benefits. The harms include disruption of lineage, family relationships and social fabric of humanity;
- The social, moral, psychological implications of human copies; and
- The possibility of interfering with male-female population dynamics.

At least three Islamic Fiqh (Jurisprudence) Councils have given permission for the use of excess IVF embryos for HESC research under certain conditions.<sup>33</sup> However,

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<sup>27</sup> The committee has a website. See <http://www.e-fatwa.gov.my/>

<sup>28</sup> The main provisions of the guidelines reflect the *Fatwa* which is found in the guidelines.

<sup>29</sup> This conference, held in Kuwait, was organised by Islamic Organisation of Medical Sciences (IOMS). The organisation comprises of scholars, doctors, scientists, social scientists and legal people

<sup>30</sup> Nordin M, 'Islamic Medical Ethics Amidst Developing Biotechnologies' at 4

<sup>31</sup> This was its 10th conference convened in Jeddah, Saudi Arabia

<sup>32</sup> Nordin M, 'Islamic Medical Ethics Amidst Developing Biotechnologies' at 5

<sup>33</sup> Ibid at 7-8

it is not permissible to deliberately create embryos, whether through IVF or SCNT, for research.<sup>34</sup> In the Medical Fiqh meeting in Kuwait in 2000, the Islamic Fiqh Association (IFA) pronounced that excess IVF embryos should be left without medical intervention to end their life naturally. If a responsible doctor suggests that creating spare embryos is necessary for the success of IVF treatment, the doctors should create the minimum number of required embryos in order to avoid the unnecessary wasting of embryos. The spare embryos can be used in stem cell research since they have yet to be ensouled and are not complete human beings. Islamic law prohibits surrogate parenting, adoption of children and adoption of human embryos. This is due to the importance of determining a child's true parentage and inheritance rights. This would free up excess embryos for research purposes since, under Islamic law, they could not be used by anyone other than by the couple who created them. As an institute said:

We believe it is a society's obligation to perform research on these extra embryos instead of discarding them.<sup>35</sup>

In the context of abortion, the Islamic jurisprudent council of Makkah Al Mukaramah, the Islamic world league,<sup>36</sup> passed a *Fatwa* which allowed abortion on condition that first, the foetus is grossly malformed with untreatable severe condition, and secondly the foetus is less than 120 days computed from moment of conception.

### **7.2.5 CONCLUSION ON ISLAMIC PERSPECTIVE**

The findings of the interview, which were based on Islamic religious texts and scholarly articles, revealed the following points. The concept of ensoulment is recognised in Islam. While it is debatable whether ensoulment occurs on 40<sup>th</sup> day or 120<sup>th</sup> day after conception, the majority of Islamic scholars adopt the latter interpretation. Either interpretation is liberal. Nevertheless, the early human embryo is granted respect from the moment of conception as it is a developing entity with potential to develop to a human being. The present *Fatwa* in Malaysia, reflecting the recommendations made in international Islamic conferences, permits the use of excess IVF embryos for HESC research but prohibits the deliberate creation of

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<sup>34</sup> Ibid at 8

<sup>35</sup> This was stated by the Islamic Institute, based in Washington DC, USA

<sup>36</sup> This was held in Makkah in 1990



human embryos for research purposes, whether through IVF techniques or SCNT technology. As the concept of ensoulment in Islam is interpreted liberally, there is a possibility that religious scholars might in future revisit the issue, and that the current *Fatwa* might be revised to permit the use of cloned embryos created by SCNT for HESC research.<sup>37</sup>

## 7.3 THE ROMAN CATHOLIC PERSPECTIVE

### 7.3.1 INTRODUCTION

Contentious subjects concerning reproduction, abortion and research on embryos have been debated within the Christian church. Within Christianity, there are many denominations with no consensus on HESC research. As it is not possible for this thesis to cover perspectives of all denominations, only the Catholic faith is considered. This section explores the Catholic perspective which has expressed the formal position taken by the Vatican.<sup>38</sup>

### 7.3.2 MORAL STATUS OF HUMAN EMBRYO

Catholicism is a monotheistic religion with a belief in one God. The main source of its teachings is the Bible and the second source is the tradition, comprising of oral and written tradition. This chapter also refers to the Vatican documents including *Donum Vitae* (the Gift of Life) 1987,<sup>39</sup> *Evangelium Vitae* (the Gospel of Life) 1995,<sup>40</sup> and *Dignitas Personae* (the Dignity of a Person) 2008.<sup>41</sup>

There are biblical passages which are interpreted to refer to the creation of human by God:

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<sup>37</sup> During the interview, Dr Musa explained that *Fatwas* are flexible and can be revised. When asked whether in future, it could be amended to permit SCNT, his response was that it would depend on the scientific progress in other countries where such research is legally permitted

<sup>38</sup> There has been no response from the Malaysian representatives of the Protestant faith for an interview despite repeated requests for an interview

<sup>39</sup> See [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_19870222\\_respect-for-human-life\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html)

<sup>40</sup> This is an encyclical written by Pope John Paul II which expresses the position of the Catholic church regarding the value and inviolability of human life including murder, abortion and euthanasia. See [http://www.vatican.va/edocs/ENG0141/\\_INDEX.HTM](http://www.vatican.va/edocs/ENG0141/_INDEX.HTM) (5 May 2010)

<sup>41</sup> See [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_20081208\\_dignitas-personae\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html) (6 May 2010)

For thou didst form my inward parts, thou didst knit me together in my mother's womb ... Thou knowest me right well; my frame was not hidden from thee, when I was being made in secret, intricately wrought in the depths of the earth, thy eyes beheld my unformed substance; ... the days that were formed for me, when as yet there was none of them.<sup>42</sup>

In these verses, the psalmist speaks of God who knows and cares for His creation right from the beginning.

Another verse says: 'We are created in the image of God.'<sup>43</sup> This verse can be interpreted to view human development in utero as the creative work of an ever-working God and the process by which an embryo develops from start to finish is the work of God. The spectrum of development reflects an act of creation with each stage of the continuum given the utmost value and therefore demands reverent protection.

The Catholic church teaches that life begins at conception. With reference to the Gospel of Life, it states:

From the time that the ovum is fertilised, a life is begun which is neither that of the father nor the mother; it is rather the life of a new human being with his own growth ... Right from fertilisation the adventure of a human life begins, and each of its capacities requires time - a rather lengthy time - to find its place to be in a position to act ... The human being is to be respected and treated as a person from the moment of conception and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life.<sup>44</sup>

In several sources of the written tradition, there are specific references made to the condemnation of the act of abortion. For instance, the Didache<sup>45</sup> commands, 'you shall not murder a child by abortion.'<sup>46</sup> The unborn embryo/ foetus is referred to as 'a child'.

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<sup>42</sup> Psalms 139: 13-16

<sup>43</sup> Genesis 1:26

<sup>44</sup> Chapter 3 at 60 of the document

<sup>45</sup> The written sources Tradition, including Didache, were the early teachings of the fathers of the church but they were not compiled into the Bible. They were post biblical and were letters written by the early church fathers, saints and scholars such as St Clement and St John Chrysostom

<sup>46</sup> 2.2 of Didache

The most recent document released by the Vatican is *Dignitas Personae*. This document, released in 2008, provides doctrinal directives on ethical controversies that have emerged since 1987, that is after *Donum Vitae* was released. In the light of scientific developments in the field of medical research, the document aims to address a range of issues which involve ethical controversies and criticised by pro-life ethicists. It affirms the Vatican's existing teachings, *Donum Vitae* and *Evangelium Vitae*. It focuses on the dignity of the human being and promotes biomedical research that is respectful of the dignity of every human being and procreation. Reproductive cloning is judged as illicit<sup>47</sup> and therapeutic cloning is also considered as contrary to human dignity.<sup>48</sup> Only licit types of stem cells are encouraged<sup>49</sup> which includes adult stem cell research.<sup>50</sup>

In the middle ages, influenced by Aristotle, the Catholic church believed that human life began at about 40 days after fertilisation.<sup>51</sup> However, as the science of the mid-1800s allowed the microscopic visualisation of sperm and eggs and the act of fertilisation, the Catholic church changed its position as illustrated in the next section.<sup>52</sup>

### 7.3.3 CATHOLIC POSITION ON HESC RESEARCH

The Vatican has adopted a strict position that the embryo obtains moral status at the moment of fertilisation and it is thereupon considered as a life. Ensoulment occurs at the time of conception and thus life starts from that moment. 'Thou shalt not kill' is a basic belief of the Christian faith enshrined in a fundamental teaching from the Ten Commandments. Thus, the position taken by the Vatican is that HESC research, whether using embryos created through IVF or through SCNT, is morally wrong and should be prohibited. This is the position adopted despite the fact that HESC research could lead to positive medical treatments and has 'healing powers'. According to the faith, to deliberately create life and then destroy it is not morally

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<sup>47</sup> 28 and 29 of document

<sup>48</sup> 30 of document

<sup>49</sup> 31 and 32 of document

<sup>50</sup> 32 of document

<sup>51</sup> This was explained by Dr Laurie Zoloth, professor of medical ethics at Northwestern University of Chicago, 'Buddhism at One with Stem Cell Research' <http://www.abc.net.au/science/news/stories/s1046974.htm> (7 May 2010)

<sup>52</sup> Ibid

acceptable.

As explained by Reverend Clarence Dass, a church pastor:

Life is considered as sacred and it should be protected utmost to the end ... life is not to be made used of or to be put to danger or exposed to risks of danger ... only God has the right to give life and to take life. There should be no human intervention and one cannot create life or take away life. The Pope said the mere probability that a human person is involved would suffice in justifying an absolutely clear prohibition of any intervention aimed at killing a human embryo.<sup>53</sup>

The Catholic faith also does not accept IVF treatment,<sup>54</sup> thus the argument that excess IVF embryos are going to be destroyed any way does not justify the use of these embryos for research. The faith interprets that life is a gift from God, created through mutual love between husband and wife and that there should be no human intervention, whether at the beginning or end of life. This means that contraception, IVF treatment, HESC research, abortion and euthanasia are not morally acceptable. In the context of abortion, the act is judged as morally wrong at any stage of the pregnancy,<sup>55</sup> the Gospel of Life says:

This evaluation of the morality of abortion is to be applied also to the recent forms of intervention on human embryos which, although carried out for purposes legitimate in themselves, inevitably involve the killing of those embryos. This is the case with experimentation on embryos, which is becoming increasingly widespread in the field of biomedical research ... Although one must uphold as licit procedures carried out on the human embryo which respect the life and integrity of the embryo and do not involve disproportionate risks for it, but rather are directed to its healing, the improvement of its condition of health or its individual survival, it must nonetheless be stated that the use of human embryos or fetuses as an object of experimentation constitutes a crime against their dignity as human beings who have right to the same respect owed to a child once born, just as to every person. This moral condemnation also regards procedures that exploit living human embryos and fetuses- sometimes specifically provided for this purpose by in vitro fertilization- either to be used as “biological material” or as providers of organs or tissues of transplant in the treatment of certain diseases. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act.<sup>56</sup>

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<sup>53</sup> Face-to-face interview with Reverend Clarence Dass, pastor of Fatima church, Kuala Lumpur, 10 January 2008, interview by Chee Kuen Foong (Patrick)

<sup>54</sup> See Donum Vitae at [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_19870222\\_respect-for-human-life\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html)

<sup>55</sup> The statements on abortion are at 61 and 62 of the document

<sup>56</sup> Chapter 3 at 63 of the document

### 7.3.4 CONCLUSION ON ROMAN CATHOLIC PERSPECTIVE

The interview revealed that the Catholic faith in Malaysia follows the official Vatican's clear, unambiguous and firm position on the innate dignity and rights of each human being from the beginning of life to its natural end.<sup>57</sup> Therefore, HESC research is considered as equivalent to infanticide and adult stem cell research is encouraged as it does not involve the destruction of human embryos. As described by Brownsword, Catholics are in the category of dignitarians in his formulation of the bioethical triangle who hold firmly and strictly to the view that human cloning, whether for reproductive or therapeutic, compromises human dignity and thus should be prohibited. They condemn cloning and stem cell research; their condemnation operates as a 'conversation stopper.'<sup>58</sup>

There are challenges to the Catholic position. There are no biblical references made which could be interpreted to conclude that ensoulment occurs at conception. In addition, while the Gospel of Life states that the beginning of life is at fertilisation, it does not take into consideration the biological definition of the early human embryo in the first 14 days that has not developed primitive streak. Secondly, the Gospel of Life refers to sperm egg fertilisation, and it has not considered that cloned embryos created through SCNT technology are not products of natural fertilisation. Various sources of the written tradition cited in this chapter make references to the condemnation of the specific act of abortion, and it is highly unlikely they were referring to the termination of an early embryo which has not reached the 14<sup>th</sup> day. In addition, these sources, written during those early days, clearly were not referring to the termination of an embryo created through modern technology.

In UK, some Roman Catholic members of the House of Lords changed their mind after visiting laboratories.<sup>59</sup> After they had seen for themselves what a four cell embryo actually is, they argued that the pre-14 day embryo should not to be fully protected by the law and they prefer to call it not an embryo but a pre-embryo.<sup>60</sup> It

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<sup>57</sup> In an interview with Reverend Clarence Dass, 10 January 2008, Kuala Lumpur

<sup>58</sup> Brownsword R, *Rights, Regulation and Technological Revolution*, Oxford University Press, New York, 2008 at 39

<sup>59</sup> Warnock M, 'Do Human Cells have Rights?' (1987) 1 *Bioethics* 9

<sup>60</sup> Ibid

is noted that Roman Catholics constitute minority in Malaysia.<sup>61</sup>

## 7.4 THE BUDDHIST PERSPECTIVE

### 7.4.1 BASIC PHILOSOPHY

Buddhism is a non-theistic religion which does not see human life or the world created by a deity. Basic teachings centre on the values of *prajna*/compassion, *karua*/ knowledge, ‘no-self’, non-injury and the relief of suffering of sentient beings. Buddhism believes in reincarnation and it:

sees a human life as coming after past rebirths in which the individual may have been a human, a heavenly being, an animal, a ghost or being suffering in hell. Future rebirths may be of any of such types, depends on the moral quality of a person’s actions, their karma ... physical cruelty is seen as likely to lead towards a hellish rebirth and generosity and kindness to a human or heavenly one ... The working of karma ... a natural process in which a volitional act is like a seed and its karmic results are like fruits.<sup>62</sup>

A Buddhist’s ultimate goal is to attain enlightenment/ awakening. This term refers to the specific awakening experience attained by the Buddha sitting under the bodhi tree. On attainment of enlightenment, it is believed that a person is free from the compulsive cycle of *samsara* of birth, suffering, death and rebirth and attains the highest happiness called *Nirvana*. Enlightenment is achieved only by the fulfilment of the *paramitas*/ perfections, when the Four Noble Truths are fully grasped and *karma* has reached cessation.

Buddhists consider the cultivation of spiritual identity as critical. Buddha warned his followers that speculation about metaphysical issues was futile because human problems of birth, old age, death and sorrow will remain regardless. The problem of distorted priorities is illustrated in a famous narrative, the Parable of the Mustard Seed.<sup>63</sup> In the parable, a lady sought out the Buddha, requesting that he restore life to her dead child. The Buddha’s reply was that cure was that she needed to prepare tea from five or six grains of mustard seed but the grain must come from a house

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<sup>61</sup> About 9.1% of Malaysia’s population are Christians and it is not known what percentage of this faith are Catholics. The official data does not indicate the breakdown of the different denominations of the faith. See <http://www.statistics.gov.my/portal/index.php?lang=en> (13 May 2010)

<sup>62</sup> Harvey P, ‘A Buddhist Perspective on Pre-implantation Genetic Diagnosis’ 485 *Bionews* 17 November 2008 – 23 November 2008

<sup>63</sup> National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (1997) at D-24

not visited by death. The woman was not able to obtain a single grain. This narrative illustrates that attention should not just be focused on bodily material life to the neglect of the cultivation of discovery of one's inner life.

The religion places importance on *ahimsa*/ non-harming, the First Precept of Buddhism. The 'Noble Eightfold Path',<sup>64</sup> promulgated by Buddha, prohibits infliction of violence or harm in sentient beings. This principle strictly prohibits acts that cause death or injury to living creatures, whether human or animals.

#### 7.4.2 POSSIBLE RESPONSE TO HESC RESEARCH

In Buddhism there is no central authority competent to pronounce on ethical dilemmas, such as whether or not to allow the destruction of embryos for HESC research, and there is no systematic consideration of these issues by Buddhist scholars.<sup>65</sup> Within the religion, different sects and groups discuss and resolve these matters at local level. There is a diversity of views by Buddhists on HESC research, rather than a Buddhist view.

Buddhism teaches the concept of reincarnation/ rebirth but not ensoulment. It teaches that human life begins at conception,<sup>66</sup> although there are interpretations that suggest Buddhism endorses reproductive cloning.<sup>67</sup> This is because of the chance human life gives to achieve enlightenment. Throughout history, Buddhist scholars have taught that, due to *karma*, the chances of being born as a human being are remote and human life is a precious opportunity to escape from *karma-samsara*/ perpetual rebirth by obeying the *dharma*/ teachings of Buddha. With Buddhist thought, the status of human being is critical because 'it is the only ontological condition by which an entity can achieve enlightenment and liberation from a world marked by suffering.'<sup>68</sup> In this respect, any form of human reproduction, whether

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<sup>64</sup> The Noble Eightfold Path is one of the fundamentals of Buddhist virtuous or moral life. The path is the way to the cessation of suffering, the fourth part of the Four Noble Truths. The symbol of the Noble Eightfold Path is an eight-spoked Dharmachakra

<sup>65</sup> Keown D, 'No Harm Applies to Stem Cell Embryos: One Buddhist's View' <http://www.beliefnet.com/News/Science-Religion/2004/04/No-Harm-Applies-To-Stem-Cell-Embryos-One-Buddhists-View.aspx> (7 May 2010)

<sup>66</sup> Ibid

<sup>67</sup> *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* at D-23

<sup>68</sup> Ibid

sexual or asexual, that allows for the birth of a human being is sacred and in reproductive cloning, no one is harmed.

However, Buddhism has strong reservations about scientific techniques that involve destruction of life, whether human or animal. The importance that Buddhism places on birth as a human being as a necessary condition of the achievement of *bodhi*/enlightenment may restrict the research. Further, the religion places importance on the principle of *ahimsa* and any research, whether involving animals or human embryos, which causes loss of life, is problematic. By virtue of its belief in reincarnation, it regards 'the new conceptus as the bearer of the karmic identity of a recently deceased individual' and therefore, it is entitled to the same moral respect as an adult human being'.<sup>69</sup> For this reason, Buddhism sees the moral issues raised by HESC research as not different from those raised by abortion and IVF treatment where there is destruction of embryos involved.

In Buddhism, taking one's life for the benefit of another is not necessarily evil in some circumstances, for instance, the death of a soldier for his country. According to the religion, there are two types of donation, life donation and enforced donation, both of which involve making life sacrifices for another person. These types of donation could be raised as justification for HESC research.<sup>70</sup> Life donation is where a *Bodhisatta*, a person who accumulates merits in order to be a buddha in the future, donates his/ her life for the benefit of another. The donation of his life is counted as a merit earned. However, in the context of consent, while the adult life donor has the full capacity to provide consent to donate his/ her life, an embryo in HESC research does not have such capacity, and it is therefore not possible for it to provide consent. The second type of donation, enforced donation, is illustrated by an example where a rape victim aborts her child; the child is described as the enforced donor. The child's sacrifice is for the benefit of the mother. In the context of HESC research, it is argued that between the two types of donation, enforced donation is a more plausible argument to justify the research.

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<sup>69</sup> Keown D, 'No Harm applies to Stem Cell Embryos: One Buddhist's View'

<sup>70</sup> Promta S, 'Human Cloning and Embryonic Stem Cell Research' (2004) 14 *Eubios Journal of Asian and International Bioethics* 197-199



### 7.4.3 CONCLUSION ON BUDDHIST PERSPECTIVE

From the interviews, in Buddhism, there is no clear rule as to the ethics of HESC research and there is scope for disagreements.<sup>71</sup> As the religion emphasises the central virtues of *prajna*/ compassion and *karua*/ knowledge, the faith may be open to advances in scientific understanding and the prospect of the development of medical treatments which alleviate human suffering. However, the religion has strong reservations about scientific techniques that involve the destruction of life for the two main reasons stated above, that are, first, the birth as a human being as a necessary condition for the attainment of *bodhi*/ enlightenment and secondly, the principle of *ahimsa* prohibits the act of harming a living creature. It can be argued that *ahimsa* refers to non-violence to sentient beings and, since an embryo is not a sentient being, there is no breach of the principle of *ahimsa* and its destruction does not attract the law of karma. As Promta argues, the ethics of human genetic research, which includes HESC research, would depend on the intention of the scientist and the use of his/ her wisdom.<sup>72</sup>

## 7.5 THE HINDU PERSPECTIVE

### 7.5.1 BASIC PHILOSOPHY

The Hindu religion is a polytheistic religion which holds a belief in many gods. The purpose of its philosophy is to extinguish human sorrow and suffering. Suffering is inborn, part of life and thus cannot be avoided.<sup>73</sup> The ultimate objective is to obtain a good life, overcome sorrow and achieve enlightenment through prayers and penance. Hinduism attributes suffering and misery to *karma*, the moral law of cause and effect, and teaches that most sufferings are caused by humans in failure to harmonise their thoughts and deeds in accordance with God's law.

Hinduism and Buddhism share many similar philosophies. Hindus believe in the concept of reincarnation. The *atman* (soul) is an eternal entity. The soul is not born; it is the body which is born. Death is defined as destruction of the body and birth is

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<sup>71</sup> Face-to-face interviews with Reverend T Sangharatana, Priest, Buddhist Maha Vihara on 16 December 2008 and Venerable Bhante Seelawansa & Venerable Bhante Pannasiri, Priests, Buddhist Maha Vihara on 18 December 2008, interviews by Chee Kuen Foong (Patrick). Also see Keown D, 'No Harm applies to Stem Cell Embryos: One Buddhist's View'

<sup>72</sup> See Promta S, 'Human Cloning and Embryonic Stem Cell Research'

<sup>73</sup> Face-to-face interview with Datuk Vaithilingam, President of the Malaysia Hindu Singam, 19 January 2008, interview by Chee Kuen Foong (Patrick)

the acquisition of a new body. While the body dies, the soul remains in perpetuity. During death, the soul has a natural way of continuing to the next phase; it moves to the next stage of life by transmitting from one body to another. The cultivation of spiritual self-awareness is an important teaching in the Hindu religion. High importance is placed on the achievement of *moksha/ nirvana*. This concept means one's union with God and it is ultimate goal in life. Such realisation liberates a person from *samsara*,<sup>74</sup> which then ends the cycle of rebirth. The religion respects the sanctity of life. Like Buddhism, one of the philosophies of the Hindu religion is *ahimsa/ non-injury of sentient beings*.<sup>75</sup> Respect for life is important, permeating all beings including animals. Consciously destroying life attracts bad *karma*.<sup>76</sup>

The concept of cloning is not new to Hinduism. There are many stories in ancient Hindu mythology and folklore of the creation of beings by some process that resembles cloning.<sup>77</sup> The narratives have references to the creation of a person or deity through cells of skin or drops of blood.<sup>78</sup> Devi Parvathi created Lord Ganesha from a fragment of her skin, a spark from Shiva's third eye created Lord Murugan and Kunti Devi conceived her sons, Pandavas, by uttering divine mantras dedicated to Gods. These creations caused the Devas and Rishis difficulties in trying to distinguish the genuine from the replicas.

### 7.5.2 POSSIBLE RESPONSE TO HESC RESEARCH

Unlike the Vatican of the Catholic faith, there is no central authority in Hindu religion that makes pronouncement of the religion's official position. The resolution of ethical dilemmas depends on the guru/ spiritual leader and in conferences, held mostly in India, the leaders of different sects give their interpretations of such issues.<sup>79</sup>

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<sup>74</sup> Samsara is a cycle of birth, death and rebirth, as a continuum. Ephemeral pleasures lead people to desire rebirth to enjoy the pleasures of a perishable body

<sup>75</sup> Many Hindus embrace vegetarianism and animal research is difficult to justify.

<sup>76</sup> The main holy book for the Hindu religion is Bhagavad Gita. The religion is in harmony with science as confirmed in the Hindu scriptures

<sup>77</sup> See <http://www.ibiblio.org/gautam/hind0006.htm> (18 May 2010)

<sup>78</sup> Letchumanan R, 'Human Cloning, A Hindu Perspective' paper presented at 'Seminar on Reproductive Cloning of Human Beings' 2002

<sup>79</sup> In an interview with Datuk Vaithilingam. 19 January 2008, Kuala Lumpur

Hindus believe that life begins at conception, the beginning of a soul's rebirth from a previous life. In the context of abortion, Hinduism is opposed to the deliberate killing of an embryo or foetus except to save the life of the mother. According to the Hindu *Vedas*/ religious texts, all lives are sacred, whether humans, animals or plants. However, according to the food chain argument, the survival of one being is at the expense of another, as explained in the following passage:

All life is sacred ... this precept that lies at the heart of the Hindu doctrine of non-violence or *ahimsa* ... However, there is a paradox in this view. The law of nature rules that we must kill in order to survive. Human beings only live ... by consuming the plants and in most cases, the animal life ... The ancient *Rishis* or divine sages, resolved this paradox by referring to the various stages of evolution of consciousness ... plants at the lowest level ... animals then followed, and finally humans were placed at the top of the evolutionary tree ... we protect the highest level ... even if we have to kill the lower levels ... the soul passes through many species ... as many as 8.4 million species - until it finally evolves to the highest level ... which is in the form of a human being. It is this human birth that can then bring about salvation from the cycle of rebirth and eventually end up with God ... The human life... the only life which offers us the chance to achieve the ultimate and final union with God ... Recognising this value, Hinduism developed Yoga and Ayurvedic to alleviate illnesses and prolong healthy life ... modern science works on the same quest.<sup>80</sup>

In Hindu mythology Dadhichi<sup>81</sup> was a sage whose bones were sought by the gods to destroy a demon. The sage gladly agreed to be sacrificed as the demon had to be eliminated for the good of the world. Instead of interpreting Dadhichi's act as suicide and condemning it, the Hindu religion glorifies him and holds that his sacrifice is for the greater good for people everywhere. In HESC research, the question to ask is whether the destruction of embryos in the research is considered as an extraordinary and unavoidable circumstance that is done for greater good. If the answer is in the affirmative, it can be interpreted that the Hindu religion may accept the research as ethically justified.

While the principle of *ahimsa* prohibits violence to sentient beings, it can be argued that an embryo is not a sentient being, and therefore the conduct of HESC research does not constitute a breach of the principle and its destruction does not attract the law of *karma*. It has been suggested that if an act could save lives, the religion may

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<sup>80</sup> Bhanol A, 'The Ethics of Stem Cell Research: a Hindu view' *Bionews* 17 October 2008

<sup>81</sup> Dadhichi's story is referred to in a number of sacred texts including Rg Veda, the Srimad Bhagavatam, Srimad Devi Bhagavatam, and the Mahabharata

regard the act as morally permissible.<sup>82</sup> HESC research, which could lead to medical treatments in future, will alleviate the sufferings of a person that will then assist him/ her to cultivate the spiritual awareness to achieve *mokhsa*.

### 7.5.3 CONCLUSION ON HINDU PERSPECTIVE

From the interview, it revealed that there is no clear rule in Hinduism as to the ethics of HESC research.<sup>83</sup> If the destruction of the embryos in the research is considered as an extraordinary and unavoidable circumstance that is done for greater good, the Hindu religion may accept the research as ethically justified. There have been no objections raised against the research. The principle of *ahimsa* refers to non-violence to sentient beings and it can be argued that an embryo is not a sentient being. As a consequence, the Hindu religion may be open to HESC research.

## 7.6 THE SIKH PERSPECTIVE

### 7.6.1 BASIC PHILOSOPHY

The Sikh religion teaches that the goal of life is that it should be lived properly under the instruction of the guru as enshrined in the holy book of the Sikh religion.<sup>84</sup> The religion teaches a person to live an exemplary existence so that he/she may merge with God. The Sikh religion is open to the progress of science and research that will enable human beings to have better lives, produce medicine to heal illnesses and restore health.<sup>85</sup>

Like Buddhism and Hinduism, the Sikh religion teaches the law of *karma* and the concept of reincarnation. The actions and reactions are universal and a person who commits bad acts attracts bad *karma*. Rewards and punishments for any act done or left undone is not limited to only one life span. For actions done or undone in previous lives, a person may suffer or enjoy in the next life. The religion teaches that the soul goes through cycles of births and deaths before it reaches the human

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<sup>82</sup> In an interview with Datuk Vaithilingam, 19 January 2008, Kuala Lumpur

<sup>83</sup> Ibid

<sup>84</sup> Sri Guru Granth Sahib is the basic religious book of the Sikh religion

<sup>85</sup> In a face-to-face interview with Harcharan Singh, President of the Gurdwara Sahib Sentul, Vice President of the Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST), 11 January 2008, interview by Chee Kuen Foong (Patrick)

form.

### **7.6.2 POSSIBLE RESPONSE TO HESC RESEARCH**

The interview revealed that in the Sikh religion, there is no official pronouncement made on the ethics of HESC research.<sup>86</sup> The central authority for the religion to pronounce on ethical positions is the Sri Akal Takhat Sahib.<sup>87</sup>

The Sikh religion teaches that life begins at conception and it is the creative work of God.<sup>88</sup> The religion takes a strong position against abortion as it is a sin to destroy lives. In the context of HESC research, it is uncertain whether it considers it as morally acceptable. While the Sikh religion has elements of Hinduism such as *karma* and reincarnation, it is difficult to state whether it might adopt a similar approach. As compared to Buddhism and Hinduism, the Sikh religion is relatively new<sup>89</sup> with limited exploration on the ethics of HESC research. It is therefore suggested that the religious leaders fully debate on these issues.

## **7.7 THE FINDINGS OF THE INTERVIEWS**

In the developed western world which is largely influenced by the Christian faith, including Australia, UK and USA, there have been many lengthy debates that their regulatory frameworks have had to be constructed to address the conflicting concerns between the value of HESC research and the moral objections. In contrast, in Malaysia there has not been the same level of debates endured in Australia, UK and USA. No specific viewpoints were expressed about any unique Malaysian perspective in the interviews conducted with the religious leaders for the purpose of this thesis, with the exception of the Islamic and Catholic faiths.

The interviews did not uncover any special concerns with the technology and the religious leaders indicated that the religious texts themselves can be relied on for guidance. These religious leaders did not express their own views, but only drew from the religious texts. Given that there are no particularly strong preconceived

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<sup>86</sup> In an interview with Harcharan Singh, 11 January 2008, Kuala Lumpur

<sup>87</sup> This is located in Amritsar, in the state of Punjab in northern India and it faces the Harimandir Sahib (the Golden Temple)

<sup>88</sup> 74 of Guru Granth Sahib

<sup>89</sup> The religion was founded about 500 years ago

views amongst the religious leaders in Malaysia about the appropriateness of stem cell research (with the exception of the Catholic community, a minority group in Malaysia), this creates a unique opportunity to construct a best practice regulatory framework which takes into consideration the different religious perspectives but is not beholden to any particularly vocal group. There are good grounds for arguing that it is preferable to create an appropriate framework at the outset than to have to develop a framework after the groups have already developed their own strongly held views on what is ethically acceptable.

While this does not preclude consultation, it means these religious groups will go into such consultations with open minds.

In a multi-cultural and multi-religious society such as Malaysia, legislating HESC research is not without challenges, with no straightforward answers to these complex questions. Therefore, in drafting contentious policies, legislation and guidelines in a pluralistic society, the involvement of different religious groups in the process is crucial. It is recommended that representatives from all major religions of the country present their respective religious views on the contentious issues in open forums. The two religious councils, the Department of Islamic Advancement of Malaysia/ Jabatan Kemajuan Islam Malaysia (JAKIM) and the Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST) should be involved in the process as their involvement assists in attaining regulatory legitimacy, the first regulatory challenge.

Subsequent to the creation of Dolly in 1997, cloning and related issues were subjects of debate in the international community. Malaysia also debated these issues and in 2002 a ‘Seminar on Reproductive Cloning of Human Beings’<sup>90</sup> was held where presentations were made by stakeholders representing a cross section of the Malaysian society including representatives of the main religions of the country.<sup>91</sup>

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<sup>90</sup> The seminar was jointly organised by Malaysian Foreign Ministry and Institute of Strategic and International Studies (ISIS) Malaysia, a government think tank organisation. It was held in a hotel in Kuala Lumpur on 6 and 7 February 2002

<sup>91</sup> The main religions that were represented were Islam, Catholicism and Hinduism

Following on from the seminar, a *Fatwa*/ legal resolution on reproductive cloning was issued in 2002 by the National Fatwa Committee of Department of Islamic Advancement of Malaysia/ Jabatan Kemajuan Islam Malaysia (JAKIM) which prohibits the practice. This was followed by a *Fatwa* on stem cell research issued in 2005 which provides:<sup>92</sup>

- The use of excess IVF embryos for research purposes is permitted provided the couple donating the embryo has provided consent and the embryo has not reached the blastocyst stage.
- The deliberate creation of an embryo by SCNT is prohibited because the principle of *sad al-zaraie* argues that it would lead to ‘other evils’, that is, the slippery slope argument.
- Preimplantation genetic diagnosis (PGD) on early embryos is permitted.
- Stem cells from adult stem cells, aborted fetuses from lawfully terminated abortions are permitted.

The interviews conducted as part of this thesis revealed that Islamic faith has adopted an official position as reflected in the *Fatwa* discussed above and the Catholic faith in Malaysia adopts the Vatican’s official position which does not permit HESC research. These two religions adopt different interpretations on when ensoulment occurs, with the Catholic faith adopting a strict position that it occurs during conception while Islam adopts a more liberal interpretation although it is still arguable within the religion whether it happens on 40<sup>th</sup> day or 120<sup>th</sup> day after conception. In contrast, the religions of Buddhism, Hinduism and Sikhism have not made formal pronouncements on their official positions on HESC research and within each of these faiths, there are opposing views on the research. Therefore, there is a need for these Dharmic faiths to fully explore and debate on these issues.

According to Brownsword, for regulators to attain regulatory legitimacy, the regulatory position that they adopt must be considered by all ethical constituencies in a society as acceptably legitimate and ethically appropriate.<sup>93</sup> Therefore, it is argued that it is essential to conduct public forums and consultations in order to

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<sup>92</sup> <http://www.islam.gov.my/portal/> (3 June 2010). These provisions of the *Fatwa* are found on at 47-51 of *Guidelines 2009*

<sup>93</sup> See Chapter 3.2.1 of this thesis

explore the contentious issues raised by HESC research fully. These forums could lead to an appreciation of a variety of different viewpoints and possibly acceptance of the ultimate regulations adopted by the regulators even when they give effect to conclusions different from one's own. While it is acknowledged that these public forums may not necessarily lead to a consensus among the different religious groups, by conducting them, the ultimate regulatory position adopted by the regulators will then be considered as 'acceptably legitimate' and 'ethically appropriate' by the society and hence regulatory legitimacy is achieved.

While there are dissensions amongst these diverse religious groups in Malaysia, the empirical data indicate that conflicts and oppositions to HESC research in the country are not as strong as they are in the western world largely influenced by the Christian faith. Therefore, it is recommended that these religious groups should be involved in open forums prior to the enactment of legislation, guidelines and policies as this will achieve regulatory legitimacy. As Kirby explains, 'the very process of consultation and public debate promote a broad community understanding of the issues, an appreciation of different viewpoints and an acceptance of any regulation adopted, even when they give effect to conclusions different from one's own.'<sup>94</sup>

## 7.8 CONCLUSION

HESC research is controversial in multi-religious Malaysia, with some faiths that teach that the early embryo must be fully protected from the moment of conception, others that adopt the liberal approach, and others not adopting a firm official position, leaving the issue open.

The Abrahamic faiths of Islam, Christianity and Judaism<sup>95</sup> share a similar trait in that they believe in the concept of ensoulment. These religions adopt different interpretations on when ensoulment occurs, with the Catholic faith taking the strict, absolutist view that ensoulment occurring at the moment of conception and Islam

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<sup>94</sup> Kirby M, 'New Frontier' in Brownsword R & Yeung K (eds), *Regulating Technologies*, Hart Publishing, Oxford & Portland, 2008, 367-388 at 387

<sup>95</sup> Judaism is not covered in this chapter. For political reasons, the religion is not officially recognised in Malaysia



adopting a liberal interpretation, even though it is debateable whether it occurs on 40<sup>th</sup> day or 120<sup>th</sup> day after conception. In Islam, the *Fatwa* approves and permits the use of only excess ART embryos but not cloned embryos in HESC research. However, *Fatwas* are flexible and with Islam's liberal interpretation of the concept of ensoulment, there might be debates in future on whether to permit SCNT research, which may lead to the amendment of the *Fatwa* to approve and permit the use of cloned embryos in research.

In contrast, the Dharmic religions of Buddhism, Hinduism and Sikhism have not adopted official positions on HESC research. It is recommended that these faiths deliberate these issues and it is hoped that each of them arrives at an official position on the research.

To attain regulatory legitimacy,<sup>96</sup> it is crucial to involve different religious groups in the process of drafting contentious policies, legislation and guidelines in a pluralistic society. Therefore, in multi-religious Malaysia, the early human embryo can still be respected with appropriate limitations, controls, safeguards and accountability through the establishment of appropriate regulatory framework.

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<sup>96</sup> See Chapter 3.2.1 of this thesis

## 8: CURRENT REGULATION OF THE USE OF HUMAN EMBRYOS: MISSING RUNGS OF BRAITHWAITE'S PYRAMIDS

### 8.1 INTRODUCTION

The Malaysian government has identified biotechnology as one of the core technologies to accelerate the transformation of the country into a fully industrialised nation and knowledge-based economy<sup>1</sup> with the biomedical sector, which includes stem cell research, as an important component.<sup>2</sup> With these ambitious plans, and for the reasons articulated throughout this thesis, it is important to establish an effective regulatory framework that is supportive of biotechnology. The *National Biotechnology Policy* (NBP), launched in 2005, provides a development framework for the industry. The policy is underpinned by nine Thrusts with Thrust 7 stating the need to:

Create an enabling environment through continuous reviews of Malaysia's regulatory framework and procedures in line with global standards and best practices ...

However, at present there is regulatory lacuna in the area of biomedical research in Malaysia.<sup>3</sup> The current regulation of stem cell research in the nation is in the form of guidelines, the *Malaysian Guidelines for Stem Cell Research and Therapy* 2009 (the *Guidelines* 2009). This chapter includes critical analysis and assessment of the current *Guidelines* 2009.<sup>4</sup> In view of the current regulatory vacuum, the pivotal issue is whether it is necessary for the Malaysian government to consider moving on to adopt a more stringent regulatory framework, including comprehensive legislation, to govern HESC research in future, to fill the regulatory gap. A legislative regulatory framework would reflect Braithwaite's responsive regulatory theory, based on his regulatory and strengths-based pyramids.

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<sup>1</sup> Malaysian Biotechnology Corporation, *The Malaysian Biotechnology Country Report* (2009/ 2010) is available online at <http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20double.pdf> at ES-1 (13 May 2010)

<sup>2</sup> The other two important sectors are agricultural biotechnology and industrial biotechnology

<sup>3</sup> Azmi I, 'The Gap between Legal and Regulatory Framework of Health and Medical Biotech Research and Development in Malaysia and the Needs of the R & D Institutes in Malaysia' (2009) *Journal of Biotechnology Law* 109-121

<sup>4</sup> Sources of information include interviews conducted with the Malaysian government bodies including the Ministry of Health and Attorney General Chambers

This chapter also examines the possible complexities that may arise if legislation is passed including a discussion of a unique constitutional issue in Malaysia and an exploration of potential conflicts, if any, with existing laws in the nation. Finally, the successful experience in Singapore, a jurisdiction which closely resembles the political, legal and social circumstances of Malaysia, will be explored as this may serve as a useful model for the Malaysian government to emulate.<sup>5</sup>

## 8.2 AMBITIOUS NATIONAL PLANS

During the tabling of the Sixth Malaysia Plan in 1991, the *Wawasan 2020*/ Vision 2020 plan<sup>6</sup> was introduced by the then Prime Minister, Tun Mahathir Mohamad, which called for the nation to achieve its vision of progressing from developing status to a fully developed/ industrialised country by the year 2020.<sup>7</sup> Mahathir outlined nine strategic ideals that Malaysia must achieve, including ‘the establishment of a scientific and progressive society’, ‘the establishment of a fully moral and ethical society’ and ‘fostering and development of a mature democratic society.’<sup>8</sup> To achieve these ideals, it is submitted that the Malaysian government may wish to consider establishing an effective regulatory framework incorporating specific and detailed legislation on research involving human embryos.

As mentioned above, biotechnology has been identified by the Malaysian government as a core technology to expedite the transformation of the nation into an industrialised country. In 2009 the biotechnology sector contributed 2.2% to Malaysia’s national gross domestic product (GDP).<sup>9</sup> Of the 349 biotechnology companies, 41% were involved in agricultural biotechnology sector, followed by

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<sup>5</sup> Despite the similarity of Singapore’s jurisdiction to Malaysia’s, the Australian regulatory regime is chosen as a comparator in this thesis because its regulatory system has developed and evolved since the early ART days in 1980s and it meets both Brownsword’s template on effective regulation of modern technologies and Braithwaite’s responsive regulation test

<sup>6</sup> The nation required an annual growth 7% over the 30-year period so that the economy would be eightfold stronger than its 1990 GDP. However, in view of the financial crisis of 2007-2010, revisions to the vision were made

<sup>7</sup> At the opening ceremony of the Biovalley Malaysia project on May 20<sup>th</sup> 2003, it was announced that the project was intended to be a test bed for new technologies which would involve the setting of three new research institutes including the National Institute for Genomics and Molecular Biology. However, in 2005, Nature reported that the plan was postponed due to the financial crisis, see Cyranoski D, ‘Malaysian Biotechnology, The Valley of Ghosts’ (2005) 436 *Nature* 620-621

<sup>8</sup> See <http://www.wawasan2020.com/> (13 May 2010)

<sup>9</sup> See *Malaysian Biotechnology Country Report* at ES-1

38.4% in healthcare biotechnology and 20.6% in industrial biotechnology.<sup>10</sup> In terms of revenue, agricultural biotechnology sector contributed 38.6%, healthcare biotechnology accounted for 31.6%, followed by industrial biotechnology at 29.8%.<sup>11</sup> In terms of investment, the total investment for agricultural biotechnology sector was US\$287.5 million, followed by US\$235.1 million in healthcare biotechnology and US\$300 million in industrial biotechnology.<sup>12</sup> Stem cell research and therapy in Malaysia is estimated to be worth US\$157 million with a year on year growth estimated at 12%.<sup>13</sup>

In 2002, a ‘Seminar on Reproductive Cloning of Human Beings’<sup>14</sup> was held. Stakeholders representing a cross section of the Malaysian society made presentations and these include doctors, scientists, government officials, academics, lawyers, ethicists and representatives of the main religions of the country.<sup>15</sup> Subsequent to the seminar, a directive was issued by the Malaysian cabinet to the Ministry of Health (MOH) to form a committee on human cloning at the national level, the National Committee on Human Cloning, to advise the Malaysian government on these issues. This Committee, which comprises of specialists from the hospitals, is headed by the Director-General of Health.<sup>16</sup>

### 8.3 CURRENT RESEARCH BEING CONDUCTED

Malaysian scientists have recently begun pursuing human embryonic stem cell (HESC) research.<sup>17</sup> Currently, most of stem cell research conducted in the nation is on haemopoietic/ adult stem cells. However, the Institute Medical Research (IMR)<sup>18</sup> is initiating a study known as ‘Derivation of Human Embryonic Stem Cell Lines’, sponsored by the MOH, which is aimed at deriving HESC lines from excess in vitro

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<sup>10</sup> Ibid

<sup>11</sup> Ibid

<sup>12</sup> Ibid

<sup>13</sup> *Malaysian Biotechnology Country Report* at 3-26

<sup>14</sup> The seminar was jointly organised by Malaysian Foreign Ministry and Institute of Strategic and International Studies (ISIS) Malaysia, a government think tank organisation. It was held in a hotel in Kuala Lumpur on 6 and 7 February 2002

<sup>15</sup> The main religions were Islam, Catholicism and Hinduism

<sup>16</sup> Face-to-face interview with Radzi bin Harun and Rushdan bin Mohamed, Senior Federal Counsels of the International Affairs Division of Attorney General's Chambers, 27 December 2007, interview by Chee Kuen Foong (Patrick)

<sup>17</sup> [http://www.moh.gov.my/images/gallery/Garispenduan/Stem\\_Cell/stem\\_cell\\_therapy.pdf](http://www.moh.gov.my/images/gallery/Garispenduan/Stem_Cell/stem_cell_therapy.pdf) at 12 (15 December 2011)

<sup>18</sup> The IMR is the research arm of the MOH. See (12 May 2010)

fertilisation (IVF) embryos to establish the first Malaysian stem cell line.<sup>19</sup> IMR collaborates with Hospital Tengku Ampuan Rahimah (HTAR) and a private international company, Stempeutics Research Malaysia (Stempeutics).<sup>20</sup> IMR collaborates with the faculty of medicine of University of Sheffield in the UK and Lembaga Penduduk dan Pembangunan Keluarga Negara (LPPKN – National Population and Family Development, an agency of the Ministry of Women) for the propagation and expansion of HESC lines.<sup>21</sup>

In Stempeutics, researchers are attempting to develop technologies for use in drug discovery and toxicity testing.<sup>22</sup> Their research areas include the derivation of HESC lines and their differentiation into neurons, cardiomyocytes, hepatocytes and pancreatic islet cells. Recently, researchers from IMR and Stempeutics have developed a multiplex PCR method for characterising HESC and their differentiated progenies.<sup>23</sup> This is a simple, rapid and inexpensive technology which holds promise as a tool to determine spontaneous differentiation of HESC. It has been reported that existing techniques have limited use because of high costs, extensive turnaround time and the need to involve highly specialised technical expertise. This new multiplex technology developed by Malaysian scientists may ultimately serve as a method to monitor the authenticity of cells in regenerative medicine as well as drug screening applications. It is anticipated that, as the Malaysian economy recovers from the Global Financial Crisis, there will be more active research conducted on all types of stem cells, including HESCs.<sup>24</sup>

As noted earlier, there is currently regulatory void in the area of biomedical research in Malaysia. In spite of grand national ambitions adopted by the nation, the Malaysian government has not devoted sufficient attention to the establishment of a

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<sup>19</sup> (12 May 2010). Metro IVF, a fertility clinic, is assisting in this programme by providing excess IVF embryos

<sup>20</sup> Face-to-face interview with Dr Nooraini Baba, Director, Medical Health Division, Ministry of Health, 10 December 2009, interview by Chee Kuen Foong (Patrick). See <http://www.stempeutics.com/html/research-Human.htm>, 'First world-class stem cell research facility launched in Malaysia, (17 May 2010 ) and (17 May 2010)

<sup>21</sup> Face-to-face interview with Dr Nooraini Baba, 10 December 2009 Putrajaya

<sup>22</sup> <http://www.stempeutics.com/> (14 December 2011)

<sup>23</sup> Mamid M et al 'Application of Multiplex PCR for Characterization of Human Embryonic Stem Cells (hESCs) and its Differentiation Process' (2010) *Journal of Biomolecular Screening* 630-643

<sup>24</sup> This view is based on the nation's ambitious biotechnology plans and policies such as the BNP

comprehensive and tight regulatory environment that supports and controls biomedical research.<sup>25</sup> The statutes applicable to the conduct of medical research predate the biotechnology era and they have not been sufficiently revised to accommodate developments or reflect changes that occurred during the biotechnology era.<sup>26</sup> At present, the only applicable regulations on stem cell research are the National Guidelines on Stem Cell Research which are explored and analysed in the following section.

## 8.4 NATIONAL GUIDELINES ON STEM CELL RESEARCH

*Guidelines on Stem Cell Research* were first issued in 2006 (*Guidelines 2006*) by the MOH.<sup>27</sup> The *Guidelines 2006* stated that the MOH recognises the importance of stem cell research and its controversies<sup>28</sup> and it ‘will undertake to encourage and promote stem cell research in Malaysia’.<sup>29</sup> The *Guidelines 2006* also stated that the MOH recognises that it is crucial for Malaysian scientists and clinicians to be involved in stem cell research within ethical guidelines.<sup>30</sup> The provisions in *Guidelines 2006* reflected the Islamic *Fatwa*<sup>31</sup> which has officially adopted this position, leaving other religions to deliberate on these issues.<sup>32</sup>

The *Guidelines 2006* provided that all stem cell research, whether involving human or animals, must be reviewed by Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) for approval to ensure ethical research and use of stem cells.<sup>33</sup> They permitted the conduct of research involving adult stem cells,<sup>34</sup> stem

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<sup>25</sup> Azmi I, ‘The Gap between Legal and Regulatory Framework of Health and Medical Biotech Research and Development in Malaysia and the Needs of the R & D Institutes in Malaysia’ at 109-110

<sup>26</sup> Ibid. The author referred to *Human Tissue Act 1974* and noted that the statute only regulates the use of human body parts from the deceased for therapeutic as well as medical education and research purposes. He further explained that the legislation is outdated and does not cover human tissues, genes and gene samples; see page 111 of the article

<sup>27</sup> [http://www.tesma.org/downloads/Guidelines\\_stemcell\\_research.pdf](http://www.tesma.org/downloads/Guidelines_stemcell_research.pdf) (13 August 2009). The document is only 18 pages and the specific guidelines on stem cell research are found on at 14, just one page. The rest of the document contains information on the science of stem cells, the ethical debates and the *Fatwa* on stem cell research

<sup>28</sup> *Guidelines 2006* at 6

<sup>29</sup> *Guidelines 2006* at 14

<sup>30</sup> *Guidelines 2006* at 6

<sup>31</sup> The *Fatwa* on stem cell research is found at 16-17 of *Guidelines 2006*. It is drafted in Malay language

<sup>32</sup> *Guidelines 2006* at 14

<sup>33</sup> *Guidelines 2006* at 14. The terms IRB and IEC are used interchangeably according to Dr Nooraini during the interview

cells derived from foetal tissues from legally performed termination of pregnancies,<sup>35</sup> non-human stem cells<sup>36</sup> and HESC derived from 64 cell lines maintained in the USA.<sup>37</sup> However, they prohibited the creation of human embryos, whether through assisted reproductive techniques (ART) or somatic cell nuclear transfer (SCNT), for the purposes of scientific research.<sup>38</sup>

In 2009, the *Guidelines 2006* were updated by the *Malaysian Guidelines for Stem Cell Research and Therapy (Guidelines 2009)*.<sup>39</sup> The *Guidelines 2009* were prepared by the Stem Cell Research and Ethics Sub-Committee of the National Stem Cell Committee in collaboration with the MOH.<sup>40</sup> Prior to the release of the *Guidelines 2009*, a workshop entitled the ‘Scientific Meeting on Stem Cell Research’ was held in 2008.<sup>41</sup> Contributions to the workshop, in the form of constructive comments on the draft Guidelines, came from the Department of Islamic Advancement of Malaysia/ Jabatan Kemajuan Islam Malaysia (JAKIM), Persatuan Perubatan Islam Malaysia, the Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST) and ‘all non-governmental organisations (NGOs)’ and ‘many more’.<sup>42</sup> These contributions from the different religious groups would appear to be a valid attempt to attain regulatory legitimacy, the first regulatory challenge outlined by Brownsword.<sup>43</sup>

During the launch of the updated *Guidelines 2009*, the Health Minister, in his opening speech, stressed on the importance of stem cell research and therapy.<sup>44</sup> The *Guidelines 2009* state that most of stem cell research being conducted in the country

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<sup>34</sup> *Guidelines 2006* at 14

<sup>35</sup> Ibid

<sup>36</sup> Ibid

<sup>37</sup> Ibid. The 64 federally funded HESC lines in USA are available for distribution to scientists throughout the world

<sup>38</sup> Ibid

<sup>39</sup> The updated *guidelines* are available on [http://www.moh.gov.my/images/gallery/Garispanduan/Stem\\_Cell/stem\\_cell\\_therapy.pdf](http://www.moh.gov.my/images/gallery/Garispanduan/Stem_Cell/stem_cell_therapy.pdf) (15 May 2010) and see Appendix 7 of this thesis

<sup>40</sup> *Guidelines 2009* at 2

<sup>41</sup> The workshop was held on 4-6 May 2008 in Kota Bahru, see 65-69 of the *Guidelines 2009*

<sup>42</sup> See acknowledgement at 70 of the *Guidelines 2009*. It is not clear in the *Guidelines 2009* which NGOs provided the comments on the draft and it is also not clear what ‘many more’ comprises of

<sup>43</sup> See Chapter 3.2.1 of this thesis

<sup>44</sup> The launch of the updated *Guidelines 2009* was held during a seminar on stem cell research and therapy in Ampang hospital, Kuala Lumpur on 20 August 2009. The Health Minister is Dato Sri Liow Tiong Lai

involves haemopoietic stem cells including bone marrow, cord blood and peripheral blood, and it is expected that researchers would be conducting HESC research in future.<sup>45</sup> However, it appears from other sources that HESC research has already begun in the country.<sup>46</sup>

Like the *Guidelines 2006*, the *Guidelines 2009* reflect the *Fatwa* on stem cell research with the incorporation of additional guidelines.<sup>47</sup> Also mirroring the *Guidelines 2006*, the *Guidelines 2009* permit the conduct of research involving adult stem cells,<sup>48</sup> stem cells derived from foetal tissues from legally performed termination of pregnancies,<sup>49</sup> non-human stem cells<sup>50</sup> and HESC cells derived from surplus IVF embryos.<sup>51</sup> The creation of human embryos, whether through ART or SCNT, for the purposes of scientific research is still prohibited.<sup>52</sup> Similarly, the *Guidelines 2009* provide that all stem cell research, whether involving human or animals, must be reviewed by an IRB or an IEC for approval to ensure ethical research and use of stem cells.<sup>53</sup> The IRB and IEC must strictly adhere to the *Guidelines 2009*. A copy of any research proposal must be submitted to the National Stem Cell Research and Ethics Sub-Committee, which retains the right to review the proposal.<sup>54</sup>

The *Guidelines 2009* prohibit the following activities:<sup>55</sup>

- research involving in vitro culture of any intact human embryo, regardless of derivation methods, for longer than 14 days or until the formation of the primitive streak, whichever occurs first;
- research in which HESC are introduced into non-human primate blastocysts or in which any HESC are introduced into human blastocysts;
- breeding of animals into which HESC have been introduced at any stage of development; and

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<sup>45</sup> *Guidelines 2009* at 12

<sup>46</sup> See 8.2 of this chapter

<sup>47</sup> The *Fatwa* is found at 47-51 of the *Guidelines 2009*

<sup>48</sup> No 5 at 30 of *Guidelines 2009*

<sup>49</sup> No 6 at 30 of *Guidelines 2009*

<sup>50</sup> No 7 at 30 of *Guidelines 2009*

<sup>51</sup> No 8 and no 9 at 30 and 31 of *Guidelines 2009*

<sup>52</sup> No 10 at 31 of *Guidelines 2009*

<sup>53</sup> No 2 at 29 of *Guidelines 2009*

<sup>54</sup> No 3 at 29 of *Guidelines 2009*

<sup>55</sup> No 15 at 35 of *Guidelines 2009*



- development of human stem cells or other cells of pluripotent nature fused with cells of non-human origin beyond 14 days, or the formation of primitive streak begins, whichever occurs first.

Consent for blastocyst donation is required from each donor at the time of donation.<sup>56</sup> Donors' consent is required to be sought again when any specific research is being considered.<sup>57</sup> They must be informed of their right to withdraw consent until the blastocyst is used in the cell line derivation.<sup>58</sup> The informed consent process, whether for the purpose of donation of gametes or blastocysts for HESC research, is required to include the following information:<sup>59</sup>

- a statement that the blastocyst of gametes will be used to derive HESC for research that may include research on human transplantation;
- a statement that the donation is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of autologous donation;
- a statement as to whether the identities of the donors will be readily ascertainable to those who derived or work with the resulting HESC lines;
- if the identities of the donors are retained, even if coded, a statement as to whether donors wish to be contacted in the future to receive information obtained through studies of the cell lines;
- an assurance that participants in research projects will follow applicable and appropriate best practices for donation, procurement, culture and storage of cells and tissues to ensure the traceability of the stem cells, traceable information must be secured to ensure confidentiality;
- a statement that derived HESC cells and / or cells lines might be kept for many years;
- a statement that the research is not intended to provide direct medical benefit to the donors except in the case of autologous donation;
- a statement that embryos will be destroyed in the process of deriving HESC cells;

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<sup>56</sup> No 13 at 32 of *Guidelines 2009*

<sup>57</sup> Ibid

<sup>58</sup> Ibid

<sup>59</sup> No 14 at 32-34 of *Guidelines 2009*

- a statement that neither consenting nor refusing to donate embryos for research will affect the quality of any future care provided to potential donors; and
- a statement of risks involved to the donors.

Other important provisions in the *Guidelines 2009* include the following:

- payment, whether in cash or in kind, for the donation of blastocyst for research purposes is prohibited;<sup>60</sup>
- the doctor responsible for the infertility treatment and the investigator proposing to use the HESC cells should not be the same person;<sup>61</sup>
- laboratories conducting stem cell research shall conform to the required guidelines for good laboratory practices.<sup>62</sup> They shall be GMP compliant as required by the National Pharmaceutical Control Board (NPCB) and shall be certified as GMP compliant by the NPCB;
- the procurement, management, storage and disposal of stem cells and tissues used in research and clinical trials must be in accordance with the national guidelines;<sup>63</sup>
- therapeutic outcomes, adverse effects and tissue integration shall be documented or reported to the National Stem Cell and Ethics Sub-Committee;<sup>64</sup> and
- all imported stem cells/ tissue products for use in clinical trials and therapy shall be GMP certified and registered by the NPCB.<sup>65</sup>

## 8.5 ASSESSMENT OF THE *GUIDELINES 2009*

The *Guidelines 2009* appear to have made significant advances to the regulation of HESC in Malaysia. First, they attempt to address a number of issues relating to stem cell research and therapy. Secondly, they were updated three years after they were first drafted and with the incorporation of additional guidelines, being more comprehensive than the *Guidelines 2006*. Thirdly, prior to the release of the

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<sup>60</sup> No 12 at 32 of *Guidelines 2009*

<sup>61</sup> No 11 at 32 of *Guidelines 2009*

<sup>62</sup> No 16 at 36 of *Guidelines 2009*

<sup>63</sup> No 18 at 37 of *Guidelines 2009*

<sup>64</sup> No 19 at 37 of *Guidelines 2009*

<sup>65</sup> No 17 at 36 of *Guidelines 2009*

guidelines, a workshop was held and constructive comments on the draft were received from NGOs and religious organisations.

However, a number of questions can be raised in relation to these *Guidelines 2009*. Unlike bills, which are debated extensively in parliament, there were no equivalent lengthy debates conducted amongst the various stakeholders prior to the release of the *Guidelines*. While a workshop was conducted, the attendees comprised mostly doctors and other professionals in medical and scientific field.<sup>66</sup> In addition, while the opportunity for constructive comments on the draft was provided to religious organisations and NGOs,<sup>67</sup> it is probable that no invitation was sent to the general public for their comments.

The *Guidelines 2009* are brief and of general application. They apply to both stem cell research and stem cell therapy. In addition, in the research context, they apply to all types of stem cell research, that is, research involving adult stem cells and non-human stem cells as well as HESC. To achieve clarity, it is recommended that each specific type of research should have its own set of regulations.

The permissibility and prohibition of the various types of stem cell research in the *Guidelines 2009* are based on the *Fatwa* but no reference is made to the religious perspectives of the other main religions practised in Malaysia.<sup>68</sup> In the *Guidelines 2006*, provision was made for other religions to be given the opportunity for deliberation,<sup>69</sup> given that an official position had already been adopted by the Islamic religion, as reflected in the *Fatwa* issued in 2005. To date, the Malaysian Catholic church has followed the official Vatican position but other religions have yet to adopt any formal position.<sup>70</sup>

The *Guidelines 2009* are silent on the following activities:

- human reproductive cloning. The *Fatwa* prohibits this practice but the *Guidelines* make no express provision on this prohibition;

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<sup>66</sup> At 65-69 of the *Guidelines 2009*

<sup>67</sup> At 70 of the *Guidelines 2009*

<sup>68</sup> See Chapter 7.7 of this thesis

<sup>69</sup> At 14 of *Guidelines 2006*

<sup>70</sup> See Chapter 7.3 of this thesis

- the use of fresh embryos in HESC research, for instance, abnormal embryos not suitable for implantation/ embryos diagnosed by pre-implantation diagnosis (PGD) as carrying a genetic disease. It is noted that the *Fatwa* permits this activity on the basis that that fresh embryos are good and important source for HESC research.<sup>71</sup> Therefore, it could be argued that the research using these embryos should be permitted and this should be expressly stated in the Guidelines; and
- the conduct of induced pluripotent stem cells (IPS) research. IPS was an important scientific breakthrough in 2006 but the guidelines, which were drafted in 2009, make no reference to this development.

IRBs and IECs are formally designated to review and approve all stem cell research. Compared to the statutory licensing process in the Australian regulatory framework, the review of stem cell research by IRB or IEC is not as strict, as the criteria imposed for the approval of the research in the guidelines are general and they are neither stringent nor comprehensive; but merely require that ‘the IRB or IEC must strictly adhere to the National Guidelines ...’<sup>72</sup> and ‘a copy of research proposal must be submitted to the National Stem Cell Research and Ethics Sub-Committee which retains the right to review the proposal’.<sup>73</sup>

The composition of IRBs or IECs is not stated in the *Guidelines 2009*. As explained in Chapter 3, it is important that the membership of such boards and committees, which make crucial decisions on the approval of stem cell research, comprise of professionals of different backgrounds. This is essential to meet the requirements of tripartism and to avoid regulatory capture.<sup>74</sup> Therefore, such boards and committees should comprise of people from a variety of backgrounds and this should be specifically provided for in the guidelines.<sup>75</sup>

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<sup>71</sup> See Chapter 7.7 of this thesis

<sup>72</sup> No 2 at 29 of *Guidelines 2009*

<sup>73</sup> No 3 at 29 of *Guidelines 2009*

<sup>74</sup> On tripartism as a means to prevent regulatory capture, see Chapter 3.3.2 of this thesis

<sup>75</sup> Like the Australian regulatory framework. See Chapters 4 to 6 of this thesis

There are no provisions in the *Guidelines 2009* for monitoring of ongoing HESC research, for instance by inspectors, to ensure compliance.<sup>76</sup> In addition, no consequences for breaching Guidelines are prescribed, and there are no enforcement powers. The *Guidelines 2009* do not provide for the need to maintain a publicly available database on approved research or the need to make regular reports to Parliament.<sup>77</sup> These formal mechanisms, which should be made available to the public through websites, ensure transparency and accountability.

The *Guidelines 2009* do not include a clause that provides for a mandatory review within a reasonable time frame. While it is acknowledged that the *Guidelines 2006* have been updated, it is crucial to make a specific provision, through a sunset clause, in the *Guidelines 2009* for a formal mandatory review in future as this involves an area which is dynamic and fast moving, as noted at Chapters 4 and 5.

In summary, in contrast to the Australian regulatory framework on cloning and stem cell research, the *Guidelines 2009* are brief and general. They do not impose strict controls and safeguards on the use of human embryos in research. They lack mechanisms aimed at transparency and accountability, which may allay public concerns, such as maintaining a publicly available database and making regular reports to Parliament which are also accessible by the public. There was no public consultation conducted prior to the release of the guidelines, there is no inspectorate system to audit the laboratories and no clause provision providing for a mandatory review of the guidelines within a reasonable time frame. It is therefore concluded that the present guidelines do not ensure regulatory legitimacy, regulatory effectiveness and regulatory connection. The next section of the chapter justifies the need to move to the next level of regulation, that is, to establish a regulatory framework that has such important features that meet such challenges.

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<sup>76</sup> Ibid  
<sup>77</sup> Ibid

## **8.6 MOVING TO THE NEXT LEVEL: ADOPTING A REGULATORY FRAMEWORK INCORPORATING LEGISLATION**

It is recommended that the Malaysian government should consider adopting a more effective regulatory framework, including comprehensive legislation, to govern HESC research. The Australian regulatory framework, which includes legislation, serves as a model for Malaysia to adopt.<sup>78</sup> Australian legislation has features mandating the following:

- a licensing system with strict criteria to fulfil before a licence is granted;
- a licensing committee that must comprise professionals representing different backgrounds;
- a monitoring system by inspectors;
- enforcement provisions including penalties imposed on scientists for breach of statutory requirements and licence conditions;
- mechanisms that promote transparency and accountability; and
- a mandatory law review within a reasonable time.

Legislation has distinct advantages as it sets clear parameters to scientists, ensures appropriate safeguards and transparency as well as accountability and allays public concerns. In addition, the adoption of legislation could assist regulators to attain regulatory legitimacy, achieve regulatory effectiveness and maintain regulatory connection.

To attain regulatory legitimacy, public debates are essential and in a democratic society, parliament, with three readings in each house, is an important forum for the conduct of formal and structured debates where contentious issues are thoroughly explored and debated in detail.<sup>79</sup> An attempt to reconcile the differences of religious interpretations in multi-religious Malaysia is, and will remain, a challenging task in an attempt to reach a consensus. Yet as a democratic country, it is necessary that

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<sup>78</sup> See Chapters 4 to 6 of this thesis

<sup>79</sup> The parliamentary debate on the bill on cloning and stem cell research in Australia is the longest debate ever held.

reasoned debates and open forums are conducted to debate the issues fully and parliament is arguably the best forum.

Like the open court, parliament is open to visitors. Like court cases which are reported, parliamentary proceedings are documented in Hansard, which is easily accessible. Parliamentary debates are broadcasted on television and radio (not live but recorded) and such debates attract media coverage which would then create public awareness of the issues in the Malaysian society.<sup>80</sup> In contrast with the *Guidelines 2009* issued by the Malaysian Ministry of Health, the extent of consultations conducted prior to its release was not as extensive and it received limited media coverage. In addition, the seminar on cloning and related issues in 2002 was held behind ‘closed doors’ and attracted little media attention. These are not equivalent to the formal, structured and lengthy parliamentary debates conducted in the open.

Therefore, in addition to public forums, it is important to have structured and formal open processes in parliament in the formulation of regulatory policy. As both Brownsword and Braithwaite argue, it is essential that some process is conducted to ensure all voices are heard.<sup>81</sup> Regulatees, including dissenting ones, should respect the regulatory regime adopted because good faith regulatory settlements deserve to be respected. Also, when regulators regulate with the grain, this could lead to regulatory effectiveness, the second regulatory challenge. This is explained by Brownsword when he emphasises that regulators should act on the basis of consensus because they will perform better when they act with the backing of regulatees rather than without it.<sup>82</sup> Thus, the ‘regulatees who internalise the regulations and their purpose outperform other regulatees who mechanically apply the prescribed standards and have not internalised the spirit of the regulations and therefore not disposed to comply or are disposed not to comply.’<sup>83</sup>

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<sup>80</sup> For instance, in Australia, the media coverage on the bill on cloning and stem cell research issues was extensive. The coverage includes news on ABC, national newspapers like the Australian and the Age and regional papers like the Mercury in Tasmania. In addition, many blogs and social sites like Facebook and Twitter have informal coverage on such news

<sup>81</sup> See Chapter 3.2.1 of this thesis

<sup>82</sup> In an interview with Brownsword, 19 November 2009, London. He referred to the example of banning smoking in public places in UK where the hearts and minds of smokers were already won when legislation was introduced

<sup>83</sup> See Chapter 3.2.2 of this thesis

To ensure regulatory effectiveness, the ability to enforce is crucial. Therefore, in the context of stem cell regulation, it is essential to include a monitoring system where inspectors are assigned the responsibility of monitoring licensees and compliance with regulatory requirements and provision for strict criminal penalties to apply to offenders. The Australian legislation on cloning and stem cell research includes these monitoring and enforcement features.<sup>84</sup> In contrast, mere guidelines do not have enforcement power and they do not provide for the consequences of breach.<sup>85</sup> The *Guidelines 2009* issued by the Malaysian Ministry of Health has no legal provisions for the monitoring of researchers' premises by inspectors or for the consequences of breach. Accordingly, adopting legislation with strict monitoring feature will better ensure regulatory effectiveness.

To maintain regulatory connection, it is important to have a clause in the legislation that mandates review within a reasonable time frame. The clause must set the terms of reference and provide that a comprehensive written report be prepared by an independent review committee that should consider a number of issues including the scope and operation of the legislation taking into account the latest developments on HESC research in the country and internationally. The clause must also provide that the review report should include recommendations about amendments in the legislation. The Australian legislation includes these requirements but in contrast, the *Guidelines 2009* issued by the Malaysian Ministry of Health include no provision for a comprehensive mandatory review.

In considering the appropriate way forward in regulating stem cell research, Malaysian regulators could apply Professor Braithwaite's responsive regulatory theory, which advocates a mix of different regulatory instruments.<sup>86</sup> The two pyramids recommended in the regulation of HESC research in Chapter 3 of this thesis comprise the regulatory strategies pyramid, or the emotional economy of shame, and the strengths-based pyramid, or the emotional economy of pride. This pyramid structure provides a useful framework to craft a systematic set of

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<sup>84</sup> See Chapters 4 to 6 of this thesis

<sup>85</sup> Dr Nooraini agrees that due to the lack of enforcement in the present guidelines on stem cell research, she favours legislation to be passed (in an interview on 10 December 2009, Putrajaya). Dr Musa is of the same opinion (in an interview on 7 January 2008, Petaling Jaya)

<sup>86</sup> This regulatory theory is explored in Chapter 3.3 of this thesis



regulations for HESC in Malaysia. The pyramid of regulatory strategies, with its various tiers, creates awareness through education and provides guidance and support through the code of practice and the guidelines scheme which complements the strict statutory licensing scheme. The strengths-based pyramid, with its features of incentives rather than punishments, provides different varieties of rewards to researchers who have clean ethical records in their conduct of research. With these two pyramids, a range of instruments, which inflict punishment and provide incentives to scientists, effectively control their conduct. As Braithwaite says, ‘It’s very important to have a mix of support and sanctions.’<sup>87</sup> It is therefore recommended that this regulatory model, which has a combination of instruments that effectively promote the regulatory purposes and a spectre of punishment in the background, is effective in Malaysia.

For the reasons discussed above, the Malaysian government could adopt a regulatory framework to govern embryo and HESC research, similar to the Australian framework. However, it is acknowledged that Malaysian regulators are likely to encounter unique challenges, recognising it may be necessary to make modifications, where necessary, for them to apply in a society with different culture. Some complexities may arise if legislation is passed and the following sections of the chapter will explore these complexities.

## **8.7 A UNIQUE FEATURE OF THE MALAYSIAN LEGAL SYSTEM: CONSTITUTIONAL DIVISION BETWEEN SECULAR LAW AND SYARIAH LAW**

The Malaysian legal system has a feature of legal pluralism, a ‘colonially inaugurated system’.<sup>88</sup> This is reflected in the constitutional provisions in the nation which may have implications for federal legislation that defines the status of the human embryo and ensoulment. This section of the chapter explores a potential constitutional issue that may arise due to Malaysia’s unique legal pluralistic system.

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<sup>87</sup> Face-to-face interview with Professor Braithwaite, social scientist, Australia National University (ANU) 19 October 2009, interview by Chee Kuen Foong (Patrick)

<sup>88</sup> This phrase was used by Amanda Whiting in Whiting A, ‘Desecularising Malaysian Law?’ in Nicholson H & Biddulph S *Examining Practice, Interrogating Theory, Comparative Legal Studies in Asia*, Brill Academic Publishers, Inc, 2008, 223-266

Malaysia is a federal constitutional elective monarchy with the King (Yang di-Pertuan Agong) as the head of state.<sup>89</sup> Its government system is modelled on the Westminster parliamentary system and its legal system is based on English common law, a legacy of British colonial rule. Prior to colonisation, the nine states on the Malay peninsula were ruled by their respective Sultans. In 1957, the federation of Malaya (formerly the Malayan Union), incorporating nine states and three straits settlement,<sup>90</sup> was formed as it gained its independence from Britain.

The Malaysian Federal Constitution (FC) is the supreme law of the land as provided under Article 4 of the FC.<sup>91</sup> After gaining independence, nine Sultans agreed to cede most of their powers to the secular federal government but retained their powers over religious matters. This is reflected in Article 3(2) of the FC which provides for the constitutional role of the state Sultans as the ‘Head of Islam in his state’.

The Ninth Schedule of the FC provides for division of matters that could be legislated within federal and state jurisdiction. Article 74(1) of the FC provides that the federal government may make laws with respect to matters enumerated in the federal list (List I) or the concurrent list (List III) of the Ninth Schedule. Article 74(2) provides that the state government may make laws with respect to matters enumerated in the state List (List II) or the concurrent List (List III) of the Ninth Schedule. Thus legislation on religious matters fall within the state unicameral legislature, called the State Legislative Assembly.

In 1988, Article 121(1A) was incorporated into the FC to mandate the constitutional division between secular law and *syariah* law. This article provides that the secular civil courts ‘shall have no jurisdiction in respect of any matter with the jurisdiction of the *syariah* court’. The interpretation of this article has caused confusion as evident in a number of recent cases brought before the courts. These controversial cases involved the contest of the jurisdictional boundaries between secular courts

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<sup>89</sup> The Agong is an elected monarch chosen from the hereditary rulers (Sultans) of nine Malay states every five years

<sup>90</sup> The three straits settlement were Penang, Malacca and Singapore

<sup>91</sup> The British rulers assisted in the drafting of the FC

and religious courts. They included custody battles in inter-faith marriages,<sup>92</sup> religious burial<sup>93</sup> and contested religious identity.<sup>94</sup> The outcomes of the cases were that the secular civil courts declined to exercise jurisdiction on religious matters. These cases illustrated that in Malaysia's plural legal system, the secular civil courts not only affirmed the parallel authority and jurisdiction of the religious *syariah* court system but also 'deferred' to their authority.<sup>95</sup> This may have implications for federal laws that define the status of the human embryo and ensoulment.

The following issue may arise, that is, if the secular federal parliament claimed jurisdiction over issues like ensoulment, this may be open to legal challenge by the state religious authorities/ *syariah* courts. It is noted, however, that the Islamic faith has adopted liberal interpretations of ensoulment. There are two schools of thought, both of which are liberal, with one school of thought that interprets ensoulment occurring on 120<sup>th</sup> day after fertilisation (majority opinion) and the other school of thought interprets it occurring on 40<sup>th</sup> day after fertilisation.<sup>96</sup> These liberal interpretations of ensoulment are reflected in the existing national *Fatwa* in Malaysia which permits HESC research using excess IVF embryos.<sup>97</sup> The *Fatwa* also mirrors the position adopted in majority of Islamic nations.<sup>98</sup> While the national *Fatwa* is not binding on the states, a state can enforce it if it issues a state *Fatwa*. If the federal parliament claimed jurisdiction on matters including

<sup>92</sup> In *Shamala a/p Sathyaseelan v Dr Jeyaganesh a/l C, Mogarajah* [2003] 6 MLJ and *Subashini a/p Rajasingam v Saravanan a/l Thangathoray* [2007] 2 MLJ 798, while the secular civil court awarded joint legal custody to both parents, the Muslim convert husband can apply to the *syariah* court for sole custody

<sup>93</sup> In *Kaliammal a/p Innasamy lwn Pengarah Jabatan Agama Islam Wilayah Persekutuan (JAWI) dan lain-lain* [2006] 1 MLJ 685, the High Court ruled that it had no power to review the finding of the *syariah* court that the deceased had converted to Islam (a matter strongly disputed by the widow) and declined to grant the widow her application of an injunction to prevent the state religious affairs police from taking custody of her husband's body to bury him according to Muslim burial rites

<sup>94</sup> In *Lina Joy v Majlis Agama Islam Wilayah Persekutuan dan lain-lain* [2007] 4 MLJ 585 (Federal Court), [2005] 6 MLJ 193 (Court of Appeal), [2004] 2 MLJ 119 (High Court), a Muslim woman fought for her right to convert to Christianity, raising Article 11 of the secular FC which provides that 'every person has the right to profess and practice his religion'. The court rejected her demand and ruled that she first needed permission to leave the Muslim faith from the state *syariah* courts, which regard deserters of the faith as apostates

<sup>95</sup> Whiting A, 'Desecularising Malaysian Law?' at 224

<sup>96</sup> See Chapter 7.2.2 of this thesis

<sup>97</sup> See Appendix 7 of this thesis

<sup>98</sup> At least three Islamic Fiqh (Jurisprudence) Councils have given permission for the use of excess IVF embryos for HESC purposes under certain conditions. However, it is not permissible to deliberately create embryos, whether through IVF or SCNT; see Chapter 7.2.4 of this thesis

ensoulment and provided the legislative provisions comply with the national *Fatwa* which is consistent with the Quran, it is argued that it is highly unlikely the state *syariah* courts would challenge the federal legislation.

It is also noted that the recent cases brought before the courts involved matters which were strictly religious. Accordingly, it seems hardly likely that the state *syariah* courts would challenge the secular federal legislation permitting HESC research using excess IVF embryos (an area which is not religious other than the issue of ensoulment).

In addition, under list II of Schedule Nine of the FC, the jurisdiction of *syariah* courts is limited only to Muslims in matters such as succession, intestate, betrothal, marriage, inheritance, divorce, dower, maintenance, adoption, apostasy, religious conversion, and custody among others. No other criminal or civil offences are under the jurisdiction of the *syariah* courts, which have a similar hierarchy to the civil courts. These provisions have important implications for the present purposes. With limited jurisdiction under the FC, the *syariah* courts could not challenge the secular federal legislation allowing HESC research using IVF embryos, in contrast to the specific matters listed under the FC which are directly related to the Islamic faith such as conversion and apostasy.

The *Fatwa* was influential in the drafting of Malaysia's National Guidelines on Stem Cell Research.<sup>99</sup> It is therefore expected that if the Malaysian secular federal Parliament decides to enact legislation to legalise and regulate HESC research using excess IVF embryos, the Parliament will refer and adhere strictly to the *Fatwa* which permits the research only if excess IVF embryos are used (as the *Fatwa* currently does not permit deliberate creation of embryos for research purposes). Accordingly, it is argued that if federal legislation is passed to allow scientists to embark on HESC research using excess IVF embryos, the state religious authorities do not have the jurisdiction under the FC to challenge the federal legislation.

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<sup>99</sup> See Chapter 8.3 of this thesis

## 8.8 THE IMPLICATIONS OF EXISTING LAWS IN MALAYSIA: THE *PENAL CODE 1936*

This section of the chapter examines the implications of existing laws in Malaysia, namely the *Penal Code 1936 (Penal Code)*,<sup>100</sup> on issues relating to the moral status of the human embryo, ensoulment and beginning of life. The focus of the discussion in this section is not to explore the criminal offences of homicide and abortion but to compare and contrast the provisions in the *Penal Code* on the penalties imposed on a convicted offender in a homicide with the penalties imposed on a convicted offender in a termination of pregnancy resulting in the killing of a foetus/ an unborn child. It is essential to compare the differences of the length of sentencing to be imposed on the criminal, if any, as these would have implications for legislation permitting HESC research which involves the destruction of the human embryo.

There are relevant sections of the code that provide for the types and lengths of sentencing to be imposed on a convicted offender in various types of homicide. First, on one end of the continuum, a person who is guilty of murder shall be punished with death penalty.<sup>101</sup> Next, a person who commits culpable homicide not amounting to murder shall be punished with imprisonment which may extend to twenty years if the act is done with the intention of causing death. But if the act is committed with the knowledge that it is likely to cause death, he/ she shall be punished with imprisonment which may extend to ten years or with fine or with both.<sup>102</sup> Finally, a person who causes the death of a person, by committing a rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment which may extend to two years or with fine or with both.<sup>103</sup>

As a matter of comparison, the relevant sections of the *Penal Code* that provide for sentencing imposed on a convicted offender in crimes involving the death of a foetus/ an unborn child are referred to. A person who causes a pregnant woman to miscarry shall be punished with imprisonment which may extend to three years or

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<sup>100</sup> The *Malaysian Penal Code* is the criminal law code enacted by the British during the colonial rule in 1936. The *Indian Penal Code*, enacted by Great Britain in 1862, was adopted wholesale in Malaysia and accordingly, their similarities are striking

<sup>101</sup> Section 302 of *Penal Code*. Capital punishment is also imposed on a convicted drug trafficker

<sup>102</sup> Section 304 of *Penal Code*

<sup>103</sup> Section 304A of *Penal Code*

with fine or with both.<sup>104</sup> A person who with intent to cause the miscarriage of a woman that causes her death shall be punished with imprisonment which may extend to ten years and shall also be liable to fine.<sup>105</sup> If the act is done without the consent of the woman shall be punished with imprisonment which may extend to twenty years. A person who commits an act with the intention of preventing the child from being born alive shall, if such act is not done in good faith for the purpose of saving the mother's life, shall be punished with imprisonment which may extend to ten years or with fine or with both.<sup>106</sup> A person who commits an act that if he/ she causes death, he would be guilty of culpable homicide and does an act which causes the death of a quick unborn child, shall be punished with imprisonment which may extend to ten years and shall also be liable to fine.<sup>107</sup>

It is evident that the various provisions in the *Penal Code*, referred to above, impose considerably more stringent sentencing on a convicted offender in a homicide than on a convicted offender responsible for the killing of an unborn foetus. The impositions of much stricter punishments on offenders in crimes against persons suggest that human lives were already then regarded to be of higher value than developing foetuses when the *Penal Code* was drafted in the 19<sup>th</sup> century.

In addition, it is noted that section 312 is amended by the *Penal Code Amendment Act 1989 (Act A727)* and this amendment also suggests that the current law in Malaysia gives precedence to a mother over her unborn developing foetus. It provides that the performance of an abortion is not a criminal offence if a medical practitioner is of the opinion, formed in good faith, that the continuance of the pregnancy would involve risk or injury to the health of the woman, greater than if her pregnancy were terminated.<sup>108</sup> The potential risk(s) or injur(ies) to the health of the pregnant woman include risks to her life, her physical health and her mental

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<sup>104</sup> Section 312 of *Penal Code*

<sup>105</sup> Section 314 of *Penal Code*

<sup>106</sup> Section 315 of *Penal Code*

<sup>107</sup> Section 316 of *Penal Code*

<sup>108</sup> See the English case of *R v Bourne* (1939) 1 KB 687 where the doctor's defence was that if abortion was not performed, the 14 year old rape victim would suffered a complete mental breakdown. McNaughten J was of the view that not only there was a right but a duty to perform the abortion

health.<sup>109</sup> The amendment to section 312 is cogent evidence that between a pregnant woman and her unborn foetus, the law in Malaysia gives priority to the former. Thus a mother's life as well as her well-being is considered more important than her unborn developing foetus. Accordingly, it is justifiable for the lesser (unborn foetus) to be sacrificed for the greater (its mother) in an abortion.<sup>110</sup>

It is also noted that the amendment to section 312 provides the doctor a wide discretion to decide whether it is appropriate in the circumstances to terminate the pregnancy. It does not stipulate the minimum time frame during which the doctor is permitted to terminate the pregnancy. The Malaysian National Fatwa Committee declared that an abortion after 120 days gestation is considered murder unless the mother's life is in danger.<sup>111</sup> This liberal *Fatwa* is in accordance with the legal position adopted in majority of Muslim nations where abortion is permitted for health and social reasons, up to the time of ensoulment.<sup>112</sup> The amendment to the *Penal Code* which confers a wide discretion on the doctor to decide whether to terminate the pregnancy is further evidence that the current law in Malaysia deems a mother's life and her well-being as more important than a foetus.

It is therefore concluded that the existing laws in Malaysia, as illustrated in the various sections of the *Penal Code*, recognise a moral status of less than full life for an unborn foetus compared to a person. The provisions in the *Penal Code* impose considerably stricter punishment on a convicted offender in a homicide than on a convicted offender responsible for the killing of an unborn victim. In addition, the 1989 amendment to the *Penal Code* permits abortion to be carried out subject to the doctor's wide discretion, if the mother's health is endangered regardless of the stage of pregnancy she is in, thus the lesser (unborn foetus) is sacrificed for the greater

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<sup>109</sup> A woman's mental health refers to her psychological well-being and common examples to illustrate are rape and incest victims

<sup>110</sup> This amendment is in accordance with Islamic jurisprudence. According to Islamic scholars, the lesser of two evils is recommended (the principle of *al-ahamm wa al-muhimm*/the more important and the less important). Thus, if the continuance of the pregnancy involves harm to the mother such as death, the Islamic law recommends the lesser of the two evils, that is, abortion; see Noor N, Aripin Mohd & Jusoff K 'The Detrimental Crime of Abortion: A Comparative Study between Malaysian Law and Common Law' (2010) *Journal of Law and Conflict Resolution* 46-52

<sup>111</sup> <http://www.e-fatwa.gov.my/fatwa-kebangsaan/hukum-menggugurkan-kandungan-mangsa-yang-dirogol> (12 December 2011)

<sup>112</sup> See Chapter 7.2.4 of this thesis

(its mother). Accordingly, it is argued that if the Malaysian government enacts legislation to legalise HESC research which involves the destructions of embryos, it would not raise any conflicts with existing legal provisions.<sup>113</sup>

The next section explores the success story in Singapore, Malaysia's closest geographical neighbour that also shares similar political, legal and social culture due to historical reasons.

## **8.9 THE EXPERIENCE IN A COMPARABLE JURISDICTION: SINGAPORE**

This sub-section of the chapter explores the experience in Malaysia's closest southern neighbour, Singapore. Given their shared legal and constitutional history as well as heritage, Singapore's political, legal and social circumstances bear resemblance to those of Malaysia's. Between 1963 and 1965, Singapore was part of the federation of the then Malaya.<sup>114</sup> This city-state has similar multi-racial/ multi-religious demographics<sup>115</sup> as well as similar legal system, institutions and common law. Given the similar multi-religious demographics, the focus of this section is to explore the extent of public consultations conducted in this nation prior to its government's adoption of one of the world's most permissive regulation on HESC research. It is beyond the scope of this section to critically analyse its regulatory system in extensive detail.

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<sup>113</sup> As explained in Chapter 2 of this thesis, the embryo is destroyed as early as day five after fertilisation in HESC research which is far earlier than the termination of a foetus in abortion which occurs at some time during the first trimester of the pregnancy or probably later

<sup>114</sup> In 1965, Singapore was forced to secede from the federation of Malaya, which then became a republic. Under the dynamic and autocratic leadership of Lee Kuan Yew, Singapore has progressed into developed nation with one of the highest GDP per capita in the world today. It has gained a reputation as the 'Switzerland of the East' and the 'First World Asian Tiger'. The successive leaders of this nation are also highly competent with the retired Lee Kuan Yew assuming the position of Senior Minister (1990-2004) and later Minister Mentor (2004-2011). Singaporean politicians are among the most well paid in the world and the least corrupt; see [http://www.transparency.org/publications/publications/other/corruption\\_perceptions\\_index\\_2011](http://www.transparency.org/publications/publications/other/corruption_perceptions_index_2011) (15 December 2011)

<sup>115</sup> According to the Singaporean Department of Statistics 2010, this tiny city-state has 5 million people. Buddhists comprise of 33%, Muslims 15%, Christians 18% and Hindus 5.1% of its population. See <http://www.singstat.gov.sg/pubn/popn/c2010sr1.html> (8 September 2011)



Singapore is one of the more aggressive countries in the world in its efforts to become a leader in HESC research. This is evident in its government's promotion of the country as a haven for the research by investing US\$500 million in the state-of-the-art biomedical research campus called Biopolis<sup>116</sup> and creating a regulatory environment that is supportive of HESC research including SCNT.

In 2000, the Singaporean Cabinet appointed the Bioethics Advisory Committee (BAC) to examine the ethical, legal and social issues arising from research on human biology and its applications with the aim to develop and recommend policies to the Ministerial Committee for Life Sciences.<sup>117</sup> It is noted that an extensive public consultation process was conducted in an effort to understand various issues, concerns and sentiments of local interest groups and the general Singaporean community.<sup>118</sup> The BAC received written submissions from religious, patient, professional, research and medical groups. In addition, the committee held dialogue sessions with various groups to discuss and understand the views. Lastly, many letters from the general public were received by the BAC.

There were consultations with local experts as well as international experts,<sup>119</sup> with interest groups,<sup>120</sup> and with the general public.<sup>121</sup> The BAC also recognised that engagement of interest groups was critical. In November 2001, the committee released a consultation paper to 39 religious and professional organisations for their views and a total of 25 written submissions were received.<sup>122</sup> These organisations were invited to attend dialogue sessions with the BAC (there were three dialogue

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<sup>116</sup> See <http://www.a-star.edu.sg/tabid/861/default.aspx> (8 September 2011). Biopolis comprises seven buildings that accommodate research institutes for multinational companies such as GlaxoSmithKline and Novartis. Singapore has attracted a number of international scientists including Alan Colman who helped clone Dolly, Edison Liu from United States National Cancer Institute and Yoshiaki Ito from Kyoto University. The Malaysian government could emulate Singaporean government's attempts in luring foreign scientists to its shores to conduct HESC research

<sup>117</sup> Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive Cloning and Therapeutic Cloning (Cloning Report) at 1

<sup>118</sup> While the Malaysian government has organised a seminar on human reproductive cloning issues, such efforts were not extensive compared to the Singaporean government's

<sup>119</sup> Cloning Report at 10. There were seven local experts and two international experts (University of Cambridge, UK and University of California, USA) comprising scientists and sociologists. Similarly, the Malaysian government could invite foreign expertise to sit in the advisory board

<sup>120</sup> Cloning Report at 12

<sup>121</sup> Ibid at 13

<sup>122</sup> Ibid at 12

sessions). In addition, three press briefings were held to inform the public of the progress of BAC's consultations with the organisations.

Since 2001, the BAC has maintained a website containing information about human stem cell research.<sup>123</sup> Comments from the public were received through the website. In addition, the BAC and the Feedback Unit of the Ministry of Community Development and Sports, jointly conducted a focus group discussion session where 39 participants were invited to attend. Members of the public were invited through the mass media to furnish their views through letters.

After extensive deliberation of community feedback, the BAC put forward its recommendations in its report 'Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive Cloning and Therapeutic Cloning' (Cloning Report) in 2002.<sup>124</sup> The report noted that:

... in a multi-racial, multi-religious and pluralistic like Singapore, public policy has to be based on a considered weighing and balancing of the spectrum of views held by various sectors. In turn, public policy would create the necessary foundation of law and regulations ...<sup>125</sup>

The BAC report is a policy document that was produced to consider whether there are serious ethical impediments in to HESC research in Singapore. It is also a consensus statement in that the recommendations are essentially practicable and regarded as generally acceptable in the context of the place and time.

The report noted that there were different responses regarding HESC research, arising largely from the divided views on the status of the human embryo.<sup>126</sup> The National Council of Churches of Singapore (NCCS) (representing Protestants),<sup>127</sup> Catholic Medical Guild of Singapore<sup>128</sup> and Sikh Association Committee<sup>129</sup> adopt

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<sup>123</sup> Ibid at 13. In the present era, websites are increasingly important sources of information and the information could be disseminated expeditiously

<sup>124</sup> See website <http://www.bioethics-singapore.org/> (2 August 2011)

<sup>125</sup> Cloning Report at 21

<sup>126</sup> These views of the religious groups regarding HESC research in Singapore are similar to the data gathered from the interviews with the religious leaders in Malaysia; see Chapter 7 of this thesis

<sup>127</sup> Cloning Report at G-3-63

<sup>128</sup> Ibid at G-3-10

the view that human life begins at the moment of conception. However, according to the Majlis Ugama Islam Singapura (MUIS), it adopts the view that human life does not begin until some time later, that is, four months after conception.<sup>130</sup> On the other end of the scale, the Buddhist Federation would support such research as it would be ethically irresponsible to deny the progress of scientific research that would benefit the general society.<sup>131</sup>

Taking into account the diversity of views on when human life begins, the BAC adopted the intermediate position that a human embryo has a special status as a potential human being but is not of the same status as a living child or adult.<sup>132</sup> The final recommendations in the report were based on the British regulatory system but have to suit local conditions. The main recommendations included the prohibition of reproductive cloning.<sup>133</sup> The BAC supported HESC research, however, the report noted that ‘the research should take place only when there is very strong scientific in, and potential medical benefit from, such research.’<sup>134</sup> The types of research permitted included cells drawn from excess ART embryos before they reached the 14<sup>th</sup> day after fertilisation<sup>135</sup> and SCNT, provided the research has received specific approval from the proposed statutory body.<sup>136</sup> The report recommended that there should be a statutory body to licence, control and monitor all human stem cell research.<sup>137</sup>

The public consultations were aimed at arriving at a regulatory system that would moderate extreme views and build on a ‘moderate majority opinion’<sup>138</sup> which

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<sup>129</sup> Ibid at G-3-12

<sup>130</sup> Ibid at G-3-71. The MUIS has issued a *Fatwa*; see <http://www.muis.gov.sg/cms/oowweb/fatwa.aspx?id=14400> (28 December 2011). It is noted that MUIS did not mention about the other school of thought which interprets that that life starts at 40th day after conception, which is nevertheless liberal as well

<sup>131</sup> Ibid at G-3-33

<sup>132</sup> Ibid at 25

<sup>133</sup> Recommendation 7

<sup>134</sup> Recommendation 3

<sup>135</sup> Recommendation 4

<sup>136</sup> Recommendation 5

<sup>137</sup> Recommendation 8

<sup>138</sup> Waldby C, ‘Singapore Biopolis: Bare Life in the City-State’(2009) *East Asian Science, Technology and Society: an International Journal* 367-383 at 375

identified the tolerable limits of the diverse views of the different religious communities.<sup>139</sup> As explained:

Singapore's bioethical position should not be characterised by a single norm, perspective or persuasion. Rather, its position should reflect the diversity of opinions directed at promoting the common good of all.<sup>140</sup>

It was noted that there was 'no clear evidence of the subjugation of a local perspective by an elite one other than an explicit preference for enabling a diversity of views over dogmatism.'<sup>141</sup> This was achieved by promoting an idea of the 'common good'/ commonality which revolved around two principles: 'just outcome' and 'sustainable'. In 'just outcome', the BAC indicated there is an obligation on the part of all institutions to respect the common good, particularly in the sharing of the costs and benefits. In 'sustainable', the BAC recognised the obligation to respect the needs of future generations. It was also observed that the debates conducted in Singapore were not heated and lacked the kind of aggressive energy present in some western countries.<sup>142</sup>

Most of the BAC's recommendations were endorsed by the Singaporean government. In 2003, the *Regulation of Biomedical Research Act 2003* was passed which permits scientists to conduct various types of biomedical research, including HESC, under strict regulation.<sup>143</sup> In 2004, the *Human Cloning and Other Prohibited Practices Act 2004* was passed by Parliament.<sup>144</sup> This Act prohibits reproductive cloning and developing embryo outside the body for more than 14 days.

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<sup>139</sup> Ho C, Capps B & Voo TC 'Stem Cell Science and its Public: The Case of Singapore' (2010) *East Asian Science, Technology and Society: an International Journal* 7-29 at 10

<sup>140</sup> Lim S & Ho C, 'The Ethical Position of Singapore on Embryonic Stem Cell Research' (2003) *SMA News* 21-24 at 21

<sup>141</sup> Ho C, Capps B & Voo TC, 'Stem Cell Science and its Public: The Case of Singapore' at 10  
<sup>142</sup> Waldby C, 'Singapore Biopolis: Bare Life in the City-State' (2009) *East Asian Science, Technology and Society: an International Journal* 367-383 at 375. A similar observation could be made in the Malaysian context; see Chapter 7.7 of this thesis

<sup>143</sup> [http://app.reach.gov.sg/Data/adm05%5Cc6%5Cp984%5Cdraft\\_BMR\\_bill.pdf](http://app.reach.gov.sg/Data/adm05%5Cc6%5Cp984%5Cdraft_BMR_bill.pdf) (7 September 2011)

<sup>144</sup> [http://www.moh.gov.sg/mohcorp/uploadedFiles/Legislation/Legislative\\_Acts\\_And\\_Guidelines/Acts\\_Concerning\\_Medical\\_Practices\\_and\\_Research/Human\\_Cloning\\_and\\_Other\\_Prohibited\\_Practices\\_Act/GG.pdf](http://www.moh.gov.sg/mohcorp/uploadedFiles/Legislation/Legislative_Acts_And_Guidelines/Acts_Concerning_Medical_Practices_and_Research/Human_Cloning_and_Other_Prohibited_Practices_Act/GG.pdf) (7 September 2011)

In recent years, the BAC released two further reports relating to HESC research. The report, 'Donation of Human Eggs for Research' (Egg Donation Report),<sup>145</sup> and 'Human-Animal Combinations in Stem Cell Research' (Cybrid Report),<sup>146</sup> were released in 2008 and 2010 respectively. Like the BAC report on cloning and HESC research in 2002, there were public consultations conducted prior to the release of both reports. Professional organisations and religious groups were invited to submit their written feedback on their views on these controversial areas. It is noted that these public consultations revealed more sophistication and depth in the ethical evaluations.

In the Egg Donation Report, only three religious groups responded with their written feedback. These were the groups representing Catholics, Protestants and Muslims. No feedback was provided by groups representing Buddhists, Hindus and Sikhs. The Catholic Medical Guild of Singapore expressed the view that as the use of human eggs are for SCNT research purposes which is in itself morally and ethically problematic, it expressed serious concerns about allowing women to donate their eggs for research.<sup>147</sup> The NCCS (representing Protestants) too echoed similar concerns about the morality of HESC research.<sup>148</sup>

In contrast, the MUIS (representing Muslims) supported the proposition that women should be permitted to donate their eggs for research purposes, albeit with caution.<sup>149</sup> The written feedback stated that Islam encourages research that advances the welfare of human beings by quoting Ibn Al-Qayyim, a Muslim legal philosopher, who stated that the *Syariah* is established to promote the well-being of humankind in this world and the hereafter. While the religion promotes public welfare/ *maslahah*, the Islamic legal maxim states "Removal of harm takes precedence over *maslahah*". This can be explained that 'if benefits and harm are probable and not certain, then the potential benefit must outweigh the potential harm, in order to warrant the pursuit of the research.' However, the feedback cautioned that the researchers must exercise care and rigour in evaluating whether a

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<sup>145</sup> See website <http://www.bioethics-singapore.org/> (2 August 2011)

<sup>146</sup> Ibid

<sup>147</sup> Egg Donation Report at C-2

<sup>148</sup> Ibid at C-28

<sup>149</sup> Ibid at C-25

potential donor is an appropriate donor as well as ensure that she is clear about the various risks involved in egg donation. As for payment of compensation to egg donors, the written feedback stated that while Islam does not permit the commodification of the human body, including eggs, it allows for compensation of an individual for a work accomplished. It further stated that the compensation should be made not only redress the burdens and inconveniences suffered by the donors but also to acknowledge their contributions to research.

As noted above, there was no feedback by the Buddhist religious group, the religion that represents the majority of Singapore's population.<sup>150</sup> Nevertheless, in the report, the BAC formed the view that women should be permitted to donate their eggs for HESC research and all research with human eggs should be regulated. On the issue of payment to egg donors, the report stated that women should not be compensated for the donation of eggs for research when these are surplus to fertility treatment. However, for women not undergoing fertility treatment but donate eggs specifically for research, the report they should be compensated for their loss of time and earnings in addition to reimbursement of expenses directly incurred in donating their eggs.

In the report, the BAC put forward seven recommendations which were as follows:

- Recommendation 1 provides that the procurement and use of human eggs for research should be regulated
- Recommendation 2 provides that genuine consent must be provided by the egg donors without any coercion or inducement and they must be provided with adequate information in an understandable/ intelligible form and given adequate time in order to make an informed decision
- Recommendation 3 provides that egg donors should be informed of their right to withdraw their consent or vary the terms of consent at any time prior to their eggs being used in research
- Recommendation 4 provides that consent from egg donors who are undergoing fertilisation treatment should be taken independently of the

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<sup>150</sup> While 'silence is not consent', it is noted that the Buddhist religion is generally supportive of HESC research, as explored in Chapter 7 of this thesis. See also the earlier BAC report on cloning and stem cell research

medical treatment team. These donors should confirm in writing that they do not require their eggs for future reproductive purposes

- Recommendation 5 provides that egg donors undergoing ovarian stimulation should be provided with prompt and full medical care if and when complications occur and this responsibility lies with the researchers and their institutions
- Recommendation 6 provides that egg donors should be compensated for loss of time and earnings as a result of the procedures required to obtain their eggs and only if the eggs were obtained specifically for research purposes and not as a result of clinical treatment. The compensation is in addition to reimbursement of expenses directly incurred in donating their eggs. The relevant regulatory authority will determine the appropriate amount of the compensation
- Recommendation 7 provides that procurement or use of human eggs from any source not consistent with the recommendations in the report should be prohibited.

These recommendations are reflected in regulation 9 of the *Licensing Terms and Conditions on Assisted Reproduction Services 2011* which now permits women to donate their eggs to research provided these strict ethical safeguards are complied with.

In the Cybrid Report, only three religious groups responded with their written feedback (like the earlier report on egg donation for research). They were the groups representing Catholics, Protestants and Muslims but no feedback was received from groups representing Buddhists, Hindus and Sikhs.

The Catholic Medical Guild of Singapore raised strong objections over the creation of cybrids. It stated:

Therefore the only consistent conclusion is that if human embryos should be absolutely respected, so should the embryonic human cybrids. They should be respected despite of our doubts about their real nature ... all the more, since we scientifically know that they are 'genetically' mainly human. The only

reasonable thing to do is to give them the benefit of the doubt and protect them with the same respect the normal human embryo deserve[s].<sup>151</sup>

It further stated that the creation of cybrids is morally wrong as it is further step down the wrong path that has started with HESC research.<sup>152</sup> It compared the creation of cybrids to human immunodeficiency virus (HIV) which has its origins in primates and stated:

These are sober reminders that there exists a distinct boundary between man and the rest of the animal kingdom; a boundary that we may cross at our peril ...<sup>153</sup>

The feedback concluded with this saying “God always forgives, Man sometimes, but Nature never”.<sup>154</sup>

The NCSS (representing Protestants) echoed the same moral concerns. It stressed that the human embryo is a human being worthy of special respect and this would include a cybrid which is 99% human.<sup>155</sup> The feedback stated: ‘The NCSS maintains that experiments involving the insertion of human nuclei into animal eggs stripped of their chromosomes should be prohibited.’<sup>156</sup>

However, the MUIS (representing Muslims) is supportive of the creation and use of cybrids for research purposes. It stated:

We find no religious objection to the purposes and objectives of this kind of research. In fact, Islam encourages research that advances the welfare of human beings ... It falls in neatly with the objective of the Syariah which is to promote the well-being of mankind to enhance life.<sup>157</sup>

The feedback has recommended for strict regulatory mechanism to be put in place for such research such as the establishment of a stem cell research oversight

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<sup>151</sup> Cybrid Report at C1-4 - C1-5

<sup>152</sup> Ibid at C1-6

<sup>153</sup> Ibid

<sup>154</sup> Ibid

<sup>155</sup> Ibid at C9-8

<sup>156</sup> Ibid at C9-17

<sup>157</sup> Ibid at C8-2



committee to oversee the research.<sup>158</sup> It stated that strict regulation should include the compliance of the 14 day limit.<sup>159</sup>

In the report, the BAC considered that cybrids to be of potential scientific value and importance to Singapore at present or in future.<sup>160</sup> The report concluded that cybrids should be permitted on scientific grounds provided a regulatory regime is in place and strict ethical requirements are complied. The BAC put forward five recommendations, consistent with international practices and guidelines, that will ensure adequate and proper oversight of the research and will allay any fear that undesired living creatures may be created. The main recommendations were recommendation 1 which provided for the establishment of a national body to review and monitor the research and recommendation 2 which provided that the creation of cybrids should be permitted only where there is strong scientific merit and potential medical benefit from the research and in addition, the cybrid should not be permitted to develop beyond 14 days and should not be put into the uterus of a human or an animal. These recommendations are reflected in regulation 10 of the *Licensing Terms and Conditions on Assisted Reproduction Services 2011*.

With majority of its population Buddhists and the third largest community Muslims (both communities support HESC research), it is not unexpected that Singapore's permissive regulatory framework on HESC research was created without considerable challenges.<sup>161</sup> In addition, the legal pluralism that causes constitutional division between secular federal law and state religious law in Malaysia does not occur in this nation.<sup>162</sup> The state has created a regulatory environment that is conducive to internationalised HESC research, in harmony with the permissive regulatory systems of other liberal nations like United Kingdom, Sweden and South Korea. This has resulted in the facilitation of international collaborations, earning the city-state a 'well-regarded place in the

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<sup>158</sup> Ibid at C8-4

<sup>159</sup> Ibid at C8-3

<sup>160</sup> Ibid at at 2

<sup>161</sup> As noted earlier, Buddhists and Muslims comprise 33% and 15% of Singapore's population respectively

<sup>162</sup> This is explained by the historical fact that as one of the three straits settlements, Singapore was then not ruled by the Sultan but by the British Governor. Accordingly, in the post-independence era, legal pluralism does not exist in the nation

global economy of stem cell scientists',<sup>163</sup> which provides confidence to international biomedical firms and venture capitalists of the sustainability of the Singaporean stem cell research.<sup>164</sup> With Singapore's autocracy, technocracy and efficiency, its government's rapid and highly organised response in creating a liberal/ permissive legal environment that is conducive to HESC research is commendable.<sup>165</sup>

As Malaysia recovers from the GFC, the former Prime Minister (Mahathir)'s grand plan of 'Biovalley Malaysia' (see 8.2 of this chapter) should be revived. His ambitious legacy must be followed through by the present as well as future leaders of the nation. The Singaporean experience, a success story, is an exemplar for the Malaysian government to emulate. Due to their strong historical and cultural links, similar strategies could be adopted in Malaysia. It is essential that the Malaysian government employ more proactive, highly organised and well-coordinated attempts to produce a setting that promotes and strictly regulates the conduct of HESC research in the country.

The Malaysian government could adopt steps, akin to the Singaporean government's attempts, to attract eminent international scientists to its shores to conduct HESC research. Foreign expertise could be invited to sit in the advisory board such as eminent researchers who are working in nations which are at the forefront of the research. To make Malaysia an attractive destination to international scientists, there should be vast financial investments in HESC research as well as the creation of a permissive regulatory regime that is supportive of the research.

As a preliminary important step, the Malaysian government could consider organising extensive public consultations of comparable nature to Singapore's consultations leading to a report with recommendations. The important aim of these consultations is to achieve regulatory legitimacy, Brownsword's first regulatory challenge. While it is acknowledged that a seminar on human reproductive cloning

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<sup>163</sup> Waldby C, 'Singapore Biopolis: Bare Life in the City-State' at 375

<sup>164</sup> Ibid

<sup>165</sup> It is conceivable that the Malaysian government could make similar efforts

issues was held in 2002 (see 8.1 of this chapter), it is noted that these attempts were not extensive compared to the Singaporean government's efforts in the conduct of large scale public consultations. In addition, the seminar explored only reproductive cloning issues and there were no explorations or debates on issues related to HESC research.

There are some important observations on the Singaporean experience on the conduct and findings of the public consultations, drawn from all three official BAC reports (Cloning Report 2002, Egg Donation Report 2008 and Cybrid Report 2010). These observations illustrate the importance of public consultations especially on controversial issues in a pluralistic society. The first observation is, according to the Cloning Report 2002, both of the Abrahamic faiths of Islam and Catholicism in Singapore, have adopted clear, unambiguous and firm positions on HESC research with the Catholic faith taking the strict approach on one end of the spectrum and Islam assuming the liberal interpretation on the other end of the spectrum (like the data gathered from the interviews in Malaysia). It is noted that the positions adopted by the Dharmic religions of Buddhism and Sikhism were also clearly stated in the Cloning Report 2002. In comparison, the data collected in the interviews in Malaysia revealed no clear and definite positions expressed by the Dharmic faiths. Accordingly, as a multi-religious society, it is imperative that extensive public consultations are conducted in Malaysia as they provide the appropriate forum to discuss the issues thoroughly among all religious communities. As evident in the Singaporean experience, such forums are essential especially for faiths that have yet to officially adopt and clearly articulate their positions on HESC research.

The next observation is pertaining to the consistent feedback provided by MUIS (representing Muslims in Singapore) which revealed liberal interpretations of Islam on these controversial issues, albeit with caution. These liberal perspectives of Islam were evident in all three BAC reports. As explored earlier, in the first BAC report (Cloning Report 2002), MUIS adopted the view that human life begins four months (120 days) after conception, which is liberal (however, it is observed that MUIS did not include in the feedback about the other school of thought which states that ensoulment occurs on the 40<sup>th</sup> day after conception, which is also liberal). The liberal views on related issues stated in the other two BAC reports

were that MUIS supported the proposition that women should be permitted to donate their eggs for research purposes, albeit with caution (Egg Donation Report 2008), and it was supportive of the creation and use of cybrids for research purposes, also with caution (Cybrids Report 2010). As explained, MUIS justified these positions by quoting Ibn Al-Qayyim, a Muslim legal philosopher, who said that Islam promotes research that enhances the welfare of people and the conduct of such research falls within the objective of the *Syariah* which is the promotion of public welfare/ *maslahah*. However, MUIS' feedback also stressed on the Islamic legal maxim stating "Removal of harm takes precedence over *maslahah*" and accordingly, it is imperative that the potential benefit exceeds the potential harm to justify the pursuit of the research. Thus, for egg donation, MUIS cautioned that researchers must exercise care in assessing whether an egg donor is an appropriate donor and in ensuring she is aware of the risks involved in the donation. As for research involving cybrids, MUIS proposed that a regulatory mechanism be set up including the establishment of an oversight committee to oversee the research.

Thus, it can be seen that these liberal but cautious views by MUIS stressed on the importance of regulation. It is evident that the submissions by MUIS were of benefit to the BAC in arriving at its recommendations in each report. Such liberal interpretations would have implications for permitting HESC research in an Islamic country with Muslim majority. In Malaysia, it is anticipated that the Jabatan Kemajuan Islam Malaysia (JAKIM), representing Muslims in Malaysia, would also adopt similar liberal perspectives on these contentious issues. However, there is still a need to receive formal submissions by JAKIM and public consultations are the appropriate forums to hear the official views of this Muslim religious group.

The final observation is that, as mentioned, the debates conducted in Singapore were not aggressive with no evidence of dominance of a single view by a vociferous group but instead the debates revealed a preference for the exploration of a diversity of views. Due to similar demographics and cultures of both nations, a similar response could be expected in a public forum in Malaysia. As revealed from the interviews with the religious leaders in Malaysia, there are no particularly strong preconceived views amongst them on HESC research. It is therefore unlikely for a particular group to dominate the discussions during the forums (however, as a

Muslim country, it is expected that ultimately, the *Fatwa* would be influential in the making of the recommendations in the report at the end of the consultation). Forums with no subjugation of only one perspective by a dominant vocal group but exhibit a preference for an exploration of different views is professional, civil and fair. Accordingly, this is a further compelling reason for public forums to be conducted in Malaysia.

In addition to organising public forums, the Malaysian government could consider developing an informative official website on stem cell research and issues relating to the research. In the present era, the internet is increasingly an important and indispensable source of data and information on websites could be disseminated expeditiously and effectively. Websites also facilitate exchange of information with interactive discussion boards and FAQs. Furthermore, the development and maintenance of a website is not onerous.

It is also noted that with reference to the demographics of Singapore, Muslims comprise only 15% of its population and yet Singapore has adopted a permissive approach to HESC research. In contrast, in Malaysia, the Muslim community constitutes 60.4% of its population. It is therefore anticipated that the resistance and objections to HESC research would not be strong in Malaysia.

It is recommended that the current and future Malaysian government could emulate the Singaporean government's successful strategies in creating a conducive environment that is supportive of HESC research, starting with organising extensive public consultations to explore and debate issues relating to HESC research and developing a website. From the observations mentioned above, it is clear that, especially in pluralistic societies, conducting public consultations to explore the various contentious issues are crucial with the main objective of attaining regulatory legitimacy, Brownsword's first regulatory challenge. With the adoption of proactive and well-coordinated measures by the Malaysian government,

it is argued that such a strategic plan would be exemplary not only for Muslim countries<sup>166</sup> but also developing nations especially emerging economies.<sup>167</sup>

## 8.10 CONCLUSION

While it acknowledged that the creation of a conducive environment for the conduct of HESC research in Malaysia is not without challenges, the successful Singaporean experience serves as an excellent model for the Malaysian government to adopt. Despite some differences found in both nations, nevertheless Singapore's jurisdiction closely resembles Malaysia's cultural, legal and political environments. Accordingly, the Malaysian government could and should emulate the Singaporean government's efforts by employing comparable strategies and the initial approach would include organising extensive and well organised public consultations of similar nature and developing a website.

This is followed by a consideration to move to adopting a regulatory framework, which includes comprehensive legislation, to govern HESC research in the future. The proposed framework for the government to adopt would comprise a pyramid of regulatory strategies and a strengths-based pyramid, incorporating a range of instruments of punishment as well as incentives to scientists to control their conduct.<sup>168</sup> Regulators should bear in mind the words of Roger Brownsword:

Regulators ... need to be clear about their objectives and smart in their approach ... the more that regulators are able to act with the grain of regulatees' values, the more likely it is that their intervention will be effective.<sup>169</sup>

As a moderate Muslim country, this plan of action serves as a model for the Muslim world. In the Middle East, Israel is the only country that has officially adopted a

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<sup>166</sup> In addition, Malaysia was then the President of Organization of the Islamic Conference (OIC). The OIC is the second largest inter-governmental organization after the United Nations which has membership of 57 states spread over four continents. The organisation is the collective voice of the Muslim world and ensuring to safeguard and project the interests of the Muslim world in the spirit of promoting international peace and harmony among various people of the world

<sup>167</sup> Interview with Dr Musa bin Nordin, 7 January 2008, Petaling Jaya

<sup>168</sup> See Chapter 3.3 of this thesis

<sup>169</sup> This is fully quoted at Chapter 3.2.2 of this thesis

liberal permissive position on HESC research.<sup>170</sup> In the next chapter, the conclusion chapter, the proposed regulatory framework to govern HESC research for adoption by the Malaysian government is unveiled.

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<sup>170</sup> This is due to Judaism's liberal interpretation of the moral status of the early human embryo, see <http://bioethics.academy.ac.il/english/report1/Report1-e.html> (15 May 2010)

## **9: CONCLUSION:**

### **CRAFTING A RESPONSIVE REGULATORY REGIME FOR USE OF HUMAN EMBRYOS IN RESEARCH IN MALAYSIA**

In order to accomplish the ideal for Malaysia's future as a fully industrialised country and knowledge-based economy in less than a decade's time, the Vision 2020 plan developed by the then Prime Minister, Tun Mahathir, in 1991 establishes the need for a scientific, progressive, mature democratic society that is also moral and ethical. With Thrust 7 of the *National Biotechnology Programme (NBP)* providing 'for the creation of an enabling environment through continuous reviews of Malaysia's regulatory framework and procedures in line with global standards and best practices,' it is necessary for the Malaysian government to consider moving to the next level, that is, to adopt an effective regulatory framework, which includes comprehensive legislation, to govern human embryonic stem cell (HESC) research. It is proposed in this chapter that the structure of the regulation to be adopted should meet Professor Brownsword's tests of effective regulation of modern technologies and should comprise a mix of different regulatory instruments which can be summed up in the design of two pyramids based on Professor Braithwaite's theory of responsive regulation.<sup>1</sup> The framework and content of the proposed regulation is modelled after the Australian regulatory framework which has evolved since the assisted reproductive days (ART) days in the 1980s.<sup>2</sup> This research is intended to provide assistance in informing government policy on stem cell research in Malaysia.

Throughout the world, embryo and HESC research is progressing rapidly. In some nations, regulation and policies have been amended, making them more liberal. In the United Kingdom (UK), a recent legislative amendment concerns the legalisation of the creation of cybrids for research purposes.<sup>3</sup> In the United States of America (USA), President Obama has reversed former President Bush's conservative

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<sup>1</sup> See Chapter 3.3 of this thesis

<sup>2</sup> See Chapters 4 to 6 of this thesis

<sup>3</sup> *Human Fertilisation and Embryology Act 2008*



policies on HESC research by signing an executive order lifting the ban on federal funding for stem cell research as well as a memorandum on scientific integrity.<sup>4</sup> In Australia, following the Legislation Review Committee Report (Lockhart Report), the regulatory framework is more enabling, flexible and responsive to societal needs. There was further legislation review in Australia at the end of 2010, with further amendments.<sup>5</sup> In Malaysia, biotechnology is an economic driving force and the unveiling of ambitious biotechnology plan is evidence of huge investments in biotechnology made by the Malaysian government including stem cell research.<sup>6</sup>

This thesis has examined the scientific importance of embryo research and HESCs as research tools. Chapter 2 concluded that HESCs have unique properties: they are capable of dividing and renewing themselves for long periods, are unspecialised and being pluripotent, and they can give rise to specialised cell types and produce all cell types in the human body.<sup>7</sup> Opponents of HESC research argue that the scientific breakthrough of induced pluripotent stem cells (IPS) means that human embryos are no longer required for research since the new technique involves reprogramming adult cells to behave like HESCs.<sup>8</sup> However, because HESCs are derived from an embryo, they are more valuable than cells from decades old skin which may have lost some gene function. Additionally, HESCs multiply indefinitely whereas IPS cells may not have the same potential.<sup>9</sup> On this basis, HESC research should still be regarded as the epitome of stem cell research.<sup>10</sup>

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<sup>4</sup> [http://www.whitehouse.gov/the\\_press\\_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-cells/d](http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-cells/d) (3 June 2010). However, recently the US District judge has blocked federal funding for HESC research. The Obama administration will appeal against the decision. See Cook M, 'Federal Embryonic Stem Cell Research Funding stopped by Black-Letter Judge' *Bioedge* (28 August 2010) <<http://www.bioedge.org/>> (30 August 2010)

<sup>5</sup> Post submission of the thesis for examination, the review took place and the committee was chaired by the Hon Peter Heerey QC. He was joined by Professor Ian Frazer, Professor Loane Skene, Dr Faye Thompson and Reverend Kevin McGovern

<sup>6</sup> See Chapter 8.1 of this thesis

<sup>7</sup> See Chapter 2.5.2 of this thesis

<sup>8</sup> Ibid. It is noted that in Australia, there is no specific law on IPS cells

<sup>9</sup> Ibid

<sup>10</sup> This is also the opinion of Dr Robert Jansen, Medical Director of Sydney IVF Ltd in a face-to-face interview on 30 October 2009, interview by Chee Kuen Foong (Patrick). However, some scientists including Ian Wilmut, do not share the same the opinion (see Chapter 2.7.6 of this thesis)

While HESC research is still provisional, scientists hypothesise that in the future stem cell therapy will have the potential to become the basis for treating diseases such as Parkinson's disease, diabetes and heart disease. The development of stem cell lines is a scientific breakthrough which has the potential to revolutionise the practice of medicine and improve the quality and length of life. Given the promise of stem cell therapies to cure many devastating diseases, it is wise to simultaneously pursue stem cell research using all types of stem cells: adult stem cells, HESCs and IPS.

In Chapter 1 of this thesis, the public concerns raised by HESC research were discussed. The paramount concern is that extraction of HESCs from human embryos involves the destruction of the embryo. There is no easy way to address this concern because the moral status of the embryo is highly contested. But as a Muslim country, the controversy is less in Malaysia compared to the western world since the religion has adopted liberal interpretations of ensoulment. Opponents of the research argue that it is immoral to destroy an embryo which is developing.

Proponents argue that an early embryo, destroyed on the fifth day after fertilisation for the purpose of the extraction of stem cells, is a hollow microscopic ball of 100-200 cells with a diameter of 0.1-0.2 millimetres which is small enough to fit into President Roosevelt's eye on the face of a US dime,<sup>11</sup> is not yet differentiated into specific tissues, let alone organs, has no sentience, has none of the attributes thought of as human, develops primitive streak only on the 14<sup>th</sup> day after conception and most of all, is not yet ensouled at that very early stage in its development.

While scientists conducting HESC research in Malaysia may generally prefer that it is free and uninhibited by regulation,<sup>12</sup> it has been argued in this thesis that there are distinct advantages in adopting strict regulation to govern such contentious research in the country. 'To be silent/to do nothing is to give green light' to scientists to

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<sup>11</sup> See Appendix 4 of this thesis

<sup>12</sup> Some nations including USA and China do not have extensive regulation on stem cell research

embark on contentious research<sup>13</sup> and by regulating biotechnology, this could ‘guard against insidious dangers of the technology’.<sup>14</sup> It is argued that under strict regulation, it is morally permissible to use early stage human embryos in research as that would not transgress moral boundaries.

However, there are challenges in regulating new technologies including stem cell technology. In crafting a proposed legislative framework for Malaysia in this thesis, Professor Brownsword’s four challenges have been used as a template.<sup>15</sup> Achieving regulatory legitimacy, regulatory effectiveness, regulatory connection and regulatory cosmopolitanism is even more acute problem for emerging technologies in an emerging economy with a multi-religious society than elsewhere. But there are ways to address each challenge albeit not without difficulties.

In achieving regulatory legitimacy, holding reasoned debates and open forums enables the exploration of such contentious issues. There should be legitimate processes to ensure all voices are heard. Resolving differences of opinions in a multi-religious society such as Malaysia remains a challenging task. While it is not reasonable to expect the religious leaders to set aside their deep religious differences at open forums, it is possible that a compromise position could be reached. The successful experience of the conduct of extensive public consultations in Singapore, which has similar demographics and culture as Malaysia, is exemplary for the Malaysian government to emulate. Any resolution should be reached as a result of ongoing dialogue between all interested parties and the dialogue must continue. In addition, if a bill is introduced in Parliament, formal structured debates will be conducted where the arguments are fully explored and debated. The procedure is crucial and is a hallmark of a democratic society. Regulators need to ensure that the processes achieve as much consensus as possible.<sup>16</sup>

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<sup>13</sup> Kirby M, ‘New Frontier’ in Brownsword R & Yeung K (eds), *Regulating Technologies*, Hart Publishing, Oxford & Portland, 2008, 367- 388 at 375. The quote is extracted more fully in Chapter 1.6

<sup>14</sup> Fukuyama F, *Our Posthuman Future* Picador, New York, 2002. The quote is extracted more fully in Chapter 1.6 of this thesis

<sup>15</sup> See Chapter 3.2 of this thesis

<sup>16</sup> This is the view of Professor Brownsword, see Chapter 3.2.1 of this thesis

It is argued that to attain regulatory effectiveness, regulators should act on the basis of consensus and adopt Professor Braithwaite's responsive regulation which advocates a mix of different regulatory instruments based on the two multi-tiered pyramids.<sup>17</sup> In addition, the appointment of inspectors to monitor research, through the conduct of regular audits to check licensees' compliance with the law, is likely to ensure regulatory effectiveness. Critics may argue that there is no guarantee that such monitoring procedure is effective due to the possible problem of regulatory capture. However, Braithwaite's concept of tripartism could solve the problem with at least two inspectors conducting the audit and different inspectors performing their audit duties over a period of time. It is therefore argued that it is crucial that inspectors are officially appointed to ensure licensees' strict compliance with the law.

Maintaining regulatory connection requires regular mandatory reviews of the law within a reasonable period to ensure that the law is kept up to date and therefore remains connected with the ever changing, evolving technology. Equally crucial is the swift implementation of any recommendations resulting from such reviews. Legislation should be amended within a reasonable time after the official release of the review report. While critics may refer to the challenge of Parliamentary timetable leading to the 'roller coaster' effect and the issues may 'swing back and forth',<sup>18</sup> the Australian experience has proven them wrong. The Lockhart review illustrates a thorough review of the legislations relating to cloning and stem cell research<sup>19</sup> as well as a swift implementation of the recommendations in the report.<sup>20</sup>

With the challenge of regulatory cosmopolitanism, the area of stem cell tourism has proven to be a challenging unexplored territory. While national regulations are not effective to prevent and control such practices, there have been international guidelines, such as the comprehensive ISSCR guidelines, issued by the society.<sup>21</sup> While states do not have a legal obligation to follow the guidelines, yet those states who do not comply with the ISSCR guidelines could have pressure exerted upon

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<sup>17</sup> See Chapter 3.2.2 of this thesis

<sup>18</sup> This is the view of Professor Brownsword, see Chapter 3.2.3 of this thesis

<sup>19</sup> The Lockhart Report reviewed both 2002 legislation, see Chapters 4 to 6 of this thesis

<sup>20</sup> The *Amendment Act 2006* was passed in the year after the release of the Lockhart Report in 2005

<sup>21</sup> See Chapter 3.2.4 of this thesis

them. They could be isolated and marginalised by their peers and excluded from the benefits that otherwise might accrue. The state too has the moral obligation of raising awareness of these issues to ensure that potential patients are properly informed of the risks involved before receiving any stem cell based treatments.

These difficulties remain as challenges in regulating any new technologies. While the issues are not easily resolvable, this does not mean that regulators should simply maintain the status quo in Malaysia. Irrespective of the challenges, it is recommended that there should be a consideration of the need to establish an effective regulatory framework to govern HESC research in the country.

It is recommended that Malaysia adopts the proposed regulatory model based on Professor Braithwaite's responsive regulation theory.<sup>22</sup> His theory is influential and is represented in the design of two pyramids supported by this thesis: the regulatory pyramid and the strengths-based pyramid.<sup>23</sup>

First, the regulatory pyramid, which comprises various tiers with the threat of punishment hovering in the background, is advantageous for the effective implementation of HESC research. Effective regulatory structure involves a mix of regulatory instruments and not a single instrument. Braithwaite's theory suggests that if a tier of the pyramid is eliminated, this results in a truncated pyramid, which is translated to a less effective strategy. An optimal mix is a combination of soft and hard law, that includes education, professional codes of practice, guidelines and legislation. Education is important as it facilitates better understanding and appreciation that promotes the observation of ethics and legal rules within the scientific community in Malaysia. Next on the rung is the application of a professional code of practice/self regulation. Scientists, like most professional bodies, adopt their own professional code of practice. This is followed by the provision of guidelines, which are flexible and can be revised easily. Finally, at the peak of the pyramid is legislation. Legislation demarcates clear parameters for

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<sup>22</sup> Professor Brownsword too has made reference to Professor's Braithwaite's theory, see Chapter 3.2.2 of this thesis

<sup>23</sup> Both pyramids are discussed in Chapter 3.3 of this thesis

scientists for ethical research and criminal sanctions are imposed to those in breach of the legislation. This ensures consistency, accountability and transparency.

Secondly, the strengths-based pyramid operates as an incentive with the effect of motivating scientists to be law compliant with the bottom rung of the pyramid being informal praise, followed by, in terms of ascendancy, formal praise, grant, escalated grant and finally, award. In the Malaysian context, it is anticipated that the strengths-based pyramid will be successful.

Critics may argue that there is no form of regulation that is universally applicable and that these theories are constructed in developed western countries and thus only applicable in the western world. Lord Denning observed regarding the applicability of English common law to a foreign country and he warned that while one could take an oak tree from English soil and plant it on Kenyan soil, he or she cannot guarantee that it would do equally well. He said:

Just as with an English oak, so with the English common law. You cannot transplant it...and expect it to retain the tough character which it has in England. It will flourish indeed, but it needs careful tending. ...In these far off lands the people must have a law which they understand and which they respect ... This wise provision should, I think, be liberally construed. It is a recognition that the common law cannot be applied in a foreign land without considerable qualification ... It has many principles of manifest justice and good sense which can be applied with advantages to people of every race and colour all the world over. But it also has many refinements, subtleties and technicalities which are not suited to other folk. These offshoots must be cut away. In these far off lands the people must have a law which they understand and which they will respect. The common law cannot fulfil this role except with considerable qualifications. The task of making these qualifications is entrusted to the judges of these lands. It is a great task. I trust that they will not fail therein.<sup>24</sup>

Since Braithwaite's responsive regulatory theory accepts that no government has the capacity to enforce all laws, it is suggested that the theory could also work in developing countries which may struggle to implement strict regulatory requirements and so in countries with weak enforcement capabilities, it is

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<sup>24</sup> *Nyali Ltd v Attorney General of Kenya* [1956] 1QB 1 at 16-17

nevertheless useful to implement regulation.<sup>25</sup> In addition, Braithwaite's concept of tripartism is his recommended solution to the problem of regulatory capture.

The legislative framework in Australia is a model that has evolved ethically, professionally and positively since the ART days in the 1980s. This thesis recommends that Malaysia adopts legislative features similar to existing Australian legislation but with modifications adapted to local conditions which make it appropriate and applicable in the country as argued by Lord Denning. Contentious research like HESC research must be subject to clear legislative parameters as these controls are essential to safeguard the public interest and allay widespread anxiety. Public confidence would be maintained with consistency, accountability, transparency and the assurance of the observance of high ethical standards by scientists conducting the research. It would mean a society with inhibiting limits and moral scruples. The features and the content of the proposed legislative framework for adoption are set out below.

1) The regulation of HESC is separate from that governing other research such as research involving adult stem cells, cells from aborted foetus and non-human stem cells.<sup>26</sup> Of these types of research, HESC is the most contentious research. It is proposed that there should be sui generis legislation to govern the use of human embryos for the purpose of extracting HESCs.

2) The proposed legislation should apply to public research, private research and collaborative research, whether between national institutions or between national and international institutions.

3) Human reproductive cloning should be prohibited and any attempt to undertake this activity should be subject to criminal penalty. This reflects the *Fatwa* issued by

<sup>25</sup> Braithwaite J, 'Responsive Regulation and Developing Economies' 43 *World Development* 888. On the relevance and applicability of his theory in the developing world, Braithwaite refers to the resolution of the 2006 East Timorese crisis; see chapter 3.3.1 of this thesis

<sup>26</sup> The guidelines in Malaysia regulate these different types of research, see Chapter 8.3 of this thesis

the National Fatwa Committee of Malaysia that human reproductive cloning is prohibited<sup>27</sup> and this is also in accordance with the position taken by the international community.<sup>28</sup>

4) A moratorium should be imposed on Somatic Cell Nuclear Transfer (SCNT) research. The *Fatwa* rules that the deliberate creation of a human embryo by SCNT for research purposes is prohibited on the basis of *sad al zaraie*/ closing all doors on evil.<sup>29</sup> It remains to be seen whether this prohibition will be lifted in the future. Arguably, SCNT will not lead to evil consequences with adequate regulation and the *syariah* aims to strike a balance between the inherent good of the act and its possible evil consequences. In addition, it is stressed that Islamic religious leaders have adopted liberal interpretations of the concept of ensoulment, with the majority interpreting that ensoulment occurs on the 120th day after conception.<sup>30</sup> In future Islamic conferences, the issue might be revisited that could lead to the issuance of a fresh *Fatwa* which would permit the creation of an embryo through the SCNT process for research purposes.<sup>31</sup>

5) The use of fresh embryos, for instance abnormal embryos not suitable for implantation or embryos diagnosed by pre-implantation diagnosis (PGD) as carrying a genetic disease should be legalised for the purposes of extracting HESC for research purposes. The *Fatwa* permits the practice of PGD.<sup>32</sup>

6) A licensing scheme should be introduced for research involving excess IVF embryos. This reflects the existing *Fatwa*,<sup>33</sup> which provides that only licensed researchers are permitted for the use of excess IVF embryos for research. The

<sup>27</sup> <http://www.islam.gov.my/portal> (3 June 2010)

<sup>28</sup> Article 11 of Universal Declaration on the Human Genome and Human Rights 1997

<sup>29</sup> <http://www.islam.gov.my/portal> (3 June 2010)

<sup>30</sup> This is discussed in Chapter 7.2.5 of this thesis. Another school of thought interpret ensoulment to occur on the 40<sup>th</sup> day after conception which is also a liberal interpretation

<sup>31</sup> This is also the opinion of Dr Musa in an interview on 7 January 2008, Petaling Jaya; see Chapter 7.2.5 of this thesis

<sup>32</sup> <http://www.islam.gov.my/portal> (3 June 2010)

<sup>33</sup> Ibid. See Chapter 7.2 of this thesis



licence should be issued by an authority like the NHMRC Licensing Committee in Australia. The legislation should establish this authority to regulate the research. This authority should be independent of the government, health authorities or research institutions.

7) Membership of the licensing body should comprise members from various backgrounds that reflect the diverse demographic groups in Malaysia. This could prevent the possible problem of regulatory capture and corruption. To resolve this problem, the concept of tripartism advocated by Professor Braithwaite explains that ‘three heads are better than two in ensuring all the arguments are properly considered, bringing about different experience and perspectives to enrich regulatory deliberation.’<sup>34</sup> Appointing a good mix of people that come from diverse backgrounds on the proposed licensing committee is a powerful deterrent to the problem of regulatory capture.<sup>35</sup>

8) Licences for research should be issued only if strict conditions are satisfied. Before issuing a licence, the licensing committee will have to be satisfied that there is approval for the research granted by an institutional research ethics review committee such as the Institutional Review Board (IRB) or the Institutional Ethics Committee (IEC).<sup>36</sup> The ethics review committee will see whether the embryos are excess to ART needs of the woman and her spouse and whether all the required consents have been obtained.

9) Consent should be provided by the egg/ embryo donor and her spouse and it should be evidenced in writing by both parties. This will also apply to unmarried

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<sup>34</sup> See Chapter 3.3.2 of this thesis

<sup>35</sup> The NHMRC Licensing Committee in Australia comprises of nine members with diverse portfolio, see Chapter 6.2 of this thesis

<sup>36</sup> In the *Guidelines 2009*, there is a provision on this; see Appendix 7 of this thesis. In view of the challenges encountered by the Human Research Committee (HREC) in Australia in understanding and performing their role with respect to consideration of licence applications (see Chapter 6.9.2 of this thesis), it is imperative that the IRB/ IEC should be provided adequate training

couples living as partners. While Islam justifies practices only within the confines of a valid marriage, it is argued that the embryos should not be wasted.

10) The licensing committee must be satisfied that the research proposal fulfils the purposes of research by the observation of the principles of necessity, that is, the research represents a significant knowledge or improvement in technologies for treatment and secondly, the principle of proportionality, that is, the number of embryos used for the research is restricted to that likely to be necessary.

11) The licensing committee should be given power by the legislation to perform all things necessary to be done in connection with the performance of its duties.<sup>37</sup>

12) Inspectors should be appointed to monitor scientists' compliance with licence conditions.<sup>38</sup> Their role is to make regular visits to licensed research premises to conduct audit. This provision is to ensure regulatory effectiveness. It is proposed that the monitoring and compliance framework be based on a model of cooperative compliance, which encourages licence holders to cooperate with the licensing body to comply with the legislation. Emphasis is placed on education and communication to promote awareness of the responsibilities of licence holders as well as inspectors and this is achieved through information exchange visits, seminars, workshops, websites and publications.<sup>39</sup> Inspectors should also be given additional powers to monitor non-licensed facilities under search warrants.

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<sup>37</sup> As explained in Chapter 6.9 of this thesis on the criticisms of the licensing system in Australia, it is noted that the power entrusted to the licensing committee (LC) under section 15 of the *Research Involving Human Embryos Act 2002 (RIHE Act 2002)* is important and necessary for LC to execute its duties effectively. A number of the criticisms raised could be resolved by the exercise of this power by the LC

<sup>38</sup> This is a natural feature of ensuring compliance with the law

<sup>39</sup> This is a feature of the Australian regulatory model which is influenced by Professor Braithwaite's theory. See Chapters 4-6 of this thesis

13) The consequence of breach of licence should be revocation of licence by the licensing committee.

14) The legislation should provide for criminal penalties such as fines and imprisonment imposed for breach of regulations.<sup>40</sup>

15) The licensing authority should have regular consultations with all stakeholders including scientists, researchers, industry and the general public. Consultations will promote awareness of the issues and encourage consensus.<sup>41</sup>

16) An annual report should be prepared to Parliament.<sup>42</sup> This ensures transparency and accountability. The reports must outline all licences issued, the purposes for which they were granted and the outcome of the research.<sup>43</sup> In addition, it is proposed that there is a publicly available database containing all current information on all licences issued as well as licence conditions.<sup>44</sup> All research should be published.

17) A clause should be incorporated in the legislation that provides for mandatory review of the legislation by an independent review committee and the review should be conducted within a reasonable time frame,<sup>45</sup> taking into considerations the latest developments of the science. The review, as well as the swift implementation of the recommendations, will ensure regulatory connection.<sup>46</sup>

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<sup>40</sup> This is the highest rung of the regulatory pyramid

<sup>41</sup> This is the lowest rung of the regulatory pyramid, that is, education. Brownsword has also expressed the importance of conducting open discussions among all stakeholders

<sup>42</sup> In Australia, the report is prepared bi yearly, that is, every six months

<sup>43</sup> This is similar to the Australian position, see Chapters 4-6 of this thesis

<sup>44</sup> Ibid

<sup>45</sup> In Australia, the review is conducted three years after the legislation came into effect; see Chapters 4-6 of this thesis

<sup>46</sup> Regulatory connection is the third challenge raised by Brownsword

The proposed regulatory framework for the Malaysian government to adopt that governs HESC research effectively should attain Brownsword's regulatory legitimacy, exhibit regulatory effectiveness and maintain regulatory connection. Together with the Braithwaite's regulatory pyramid (emotional economy of shame), incorporating a range of regulatory instruments, employed as 'sticks' to inflict punishments and his other pyramid, the strengths-based pyramid (emotional economy of pride), comprising a variety of rewards/ incentives which serve as 'carrots' and thereby promotes the regulatory purposes, these are effective means of controlling the conduct of scientists embarking HESC research in Malaysia. With a spectre of punishment threatening in the background but never threatened in the foreground, Braithwaite's 'Benign Big Guns' project an image of invisibility by carrying different varieties of big sticks as well as giving away various incentives. They could and would achieve success by walking and speaking softly.

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# **APPENDIX 1**

## **INTERVIEWEES**

The following people were interviewed:

### **MALAYSIA:**

- Dr Khairi Yaacob (Director, Medical Health Division, Ministry of Health) 14 January 2008
- Dr Nooraini Baba (Director, Medical Health Division, Ministry of Health) 10 December 2009
- Encik Radzi bin Harun (Senior Federal Counsel of the International Affairs Division of Attorney General's Chambers) 27 December 2007
- Encik Rushdan bin Mohamed (Senior Federal Counsel of the International Affairs Division of Attorney General's Chambers) 27 December 2007
- Dr Musa bin Nordin (President of the Federation of Islam Medical Association) 7 January 2008
- Reverend Clarence Dass (Pastor of Fatima church) 10 January 2008
- Venerable Bhante Seelawansa (Priest, Buddhist Maha Vihara) 18 December 2008
- Venerable Bhante Pannasiri (Priest, Buddhist Maha Vihara) 18 December 2008
- Reverend T Sangharatana (Priest, Buddhist Maha Vihara) 16 December 2008
- Datuk Vaithilingam (President of the Malaysia Hindu Singam) 19 January 2008
- Mr Harcharan Singh (President of the Gurdwara Sahib Sentul, Vice President of the Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism) 11 January 2008

### **AUSTRALIA:**

- Professor John Braithwaite (Australian National University) (ANU) 19 October 2009

- Professor Loane Skene (Deputy Chair of Lockhart Committee) 7 August 2009
- Dr Robert Jansen (Medical Director of Sydney IVF Ltd) 30 October 2009

**UNITED KINGDOM:**

- Professor Roger Brownsword (Kings College London) 19 November 2009
- Professor Derek Morgan (University of Sheffield) 24 November 2009
- Professor Aurora Plomer (University of Sheffield) 24 November 2009

## APPENDIX 2

### GLOSSARY

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**Adult stem cell**—See [somatic stem cell](#)

**Astrocyte**—A type of supporting (glial) cell found in the nervous system

**Blastocoel**—The fluid-filled cavity inside the [blastocyst](#), an early, preimplantation stage of the developing embryo

**Blastocyst**—A [preimplantation](#) embryo of about 150 cells produced by cell division following fertilization. The blastocyst is a sphere made up of an outer layer of cells (the [trophoblast](#)), a fluid-filled cavity (the [blastocoel](#)), and a cluster of cells on the interior (the [inner cell mass](#))

**Bone marrow stromal cells**—A population of cells found in bone marrow that are different from blood cells

**Bone marrow stromal stem cells (skeletal stem cells)**—A multipotent subset of bone marrow stromal cells able to form bone, cartilage, stromal cells that support blood formation, fat, and fibrous tissue

**Cell-based therapies**—Treatment in which stem cells are induced to [differentiate](#) into the specific cell type required to repair damaged or destroyed cells or tissues

**Cell culture**—Growth of cells [in vitro](#) in an artificial medium for research or medical treatment

**Cell division**—Method by which a single cell divides to create two cells. There are two main types of cell division depending on what happens to the chromosomes: [mitosis](#) and [meiosis](#)

**Chromosome**—A structure consisting of DNA and regulatory proteins found in the nucleus of the cell. The DNA in the nucleus is usually divided up among several chromosomes. The number of chromosomes in the nucleus varies depending on the species of the organism. Humans have 46 chromosomes

**Clone**—(v) To generate identical copies of a region of a DNA molecule or to generate genetically identical copies of a cell, or organism; (n) The identical molecule, cell, or organism that results from the cloning process

1. In reference to DNA: To clone a gene, one finds the region where the gene resides on the DNA and copies that section of the DNA using laboratory techniques
2. In reference to cells grown in a tissue culture dish: a clone is a line of cells that is genetically identical to the originating cell. This cloned line is produced by cell division (mitosis) of the original cell
3. In reference to organisms: Many natural clones are produced by plants and (mostly invertebrate) animals. The term clone may also be used to refer to an animal produced by [somatic cell nuclear transfer \(SCNT\)](#) or [parthenogenesis](#)

**Cloning**—See [Clone](#)

**Cord blood stem cells**—See [Umbilical cord blood stem cells](#)

**Culture medium**—The liquid that covers cells in a culture dish and contains nutrients to nourish and support the cells. Culture medium may also include growth factors added to produce desired changes in the cells

**Differentiation**—The process whereby an unspecialized embryonic cell acquires the features of a specialized cell such as a heart, liver, or muscle cell. Differentiation is controlled by the interaction of a cell's genes with the physical and chemical conditions outside the cell, usually through signaling pathways involving proteins embedded in the cell surface

**Directed differentiation**—The manipulation of stem cell culture conditions to induce differentiation into a particular cell type



**DNA**—Deoxyribonucleic acid, a chemical found primarily in the nucleus of cells. DNA carries the instructions or blueprint for making all the structures and materials the body needs to function. DNA consists of both [genes](#) and non-gene DNA in between the genes

**Ectoderm**—The outermost [germ layer](#) of cells derived from the [inner cell mass](#) of the [blastocyst](#); gives rise to the nervous system, sensory organs, skin, and related structures

**Embryo**—In humans, the developing organism from the time of [fertilization](#) until the end of the eighth week of gestation, when it is called a [fetus](#)

**Embryoid bodies**—Rounded collections of cells that arise when [embryonic stem cells](#) are cultured in suspension. Embryoid bodies contain cell types derived from all 3 [germ layers](#)

**Embryonic germ cells**—[Pluripotent](#) stem cells that are derived from early germ cells (those that would become sperm and eggs). Embryonic germ cells (EG cells) are thought to have properties similar to embryonic stem cells

**Embryonic stem cells**—Primitive ([undifferentiated](#)) cells derived from a 5-day [preimplantation](#) embryo that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary [germ layers](#)

**Embryonic stem cell line**—Embryonic stem cells, which have been cultured under [in vitro](#) conditions that allow [proliferation](#) without [differentiation](#) for months to years

**Endoderm**—The innermost layer of the cells derived from the [inner cell mass](#) of the [blastocyst](#); it gives rise to lungs, other respiratory structures, and digestive organs, or generally "the gut"

**Enucleated**—Having had its nucleus removed

**Epigenetic**—Having to do with the process by which regulatory proteins can turn genes on or off in a way that can be passed on during cell division

**Feeder layer**—Cells used in co-culture to maintain [pluripotent](#) stem cells. For [human embryonic stem cell](#) culture, typical feeder layers include mouse embryonic fibroblasts (MEFs) or human embryonic fibroblasts that have been treated to prevent them from dividing

**Fertilization**—The joining of the male [gamete](#) (sperm) and the female gamete (egg)

**Fetus**—In humans, the developing human from approximately eight weeks after conception until the time of its birth

**Gamete**—An egg (in the female) or sperm (in the male) cell. See also [Somatic cell](#)

**Gastrulation**—The process in which cells proliferate and migrate within the embryo to transform the [inner cell mass](#) of the [blastocyst](#) stage into an [embryo](#) containing all three primary [germ layers](#)

**Gene**—A functional unit of heredity that is a segment of DNA found on chromosomes in the nucleus of a cell. Genes direct the formation of an enzyme or other protein

**Germ layers**—After the [blastocyst](#) stage of embryonic development, the [inner cell mass](#) of the blastocyst goes through [gastrulation](#), a period when the inner cell mass becomes organized into three distinct cell layers, called germ layers. The three layers are the [ectoderm](#), the [mesoderm](#), and the [endoderm](#)

**Hematopoietic stem cell**—A stem cell that gives rise to all red and white blood cells and platelets

**Human embryonic stem cell (hESC)**—A type of [pluripotent](#) stem cell derived from the [inner cell mass \(ICM\)](#) of the [blastocyst](#)

**Induced pluripotent stem cell (iPSC)**—A type of pluripotent stem cell, similar to an embryonic stem cell, formed by the introduction of certain embryonic genes into a somatic cell

***In vitro***—Latin for "in glass"; in a laboratory dish or test tube; an artificial environment

***In vitro* fertilization**—A technique that unites the egg and sperm in a laboratory instead of inside the female body

**Inner cell mass (ICM)**—The cluster of cells inside the [blastocyst](#). These cells give rise to the [embryo](#) and ultimately the [fetus](#). The ICM cells are used to generate [embryonic stem cells](#)

**Long-term self-renewal**—The ability of stem cells to replicate themselves by dividing into the same non-specialized cell type over long periods (many months to years) depending on the specific type of stem cell

**Mesenchymal stem cells**—A term that is currently used to define non-blood adult stem cells from a variety of tissues, although it is not clear that mesenchymal stem cells from different tissues are the same

**Meiosis**—The type of [cell division](#) a diploid germ cell undergoes to produce [gametes](#) (sperm or eggs) that will carry half the normal [chromosome](#) number. This is to ensure that when [fertilization](#) occurs, the fertilized egg will carry the normal number of chromosomes rather than causing aneuploidy (an abnormal number of chromosomes)

**Mesoderm**—Middle layer of a group of cells derived from the [inner cell mass](#) of the [blastocyst](#); it gives rise to bone, muscle, connective tissue, kidneys, and related structures

**Microenvironment**—The molecules and compounds such as nutrients and growth factors in the fluid surrounding a cell in an organism or in the laboratory, which play an important role in determining the characteristics of the cell

**Mitosis**—The type of [cell division](#) that allows a population of cells to increase its numbers or to maintain its numbers. The number of [chromosomes](#) remains the same in this type of cell division

**Multipotent**—Having the ability to develop into more than one cell type of the body. See also [pluripotent](#) and [totipotent](#)

**Neural stem cell**—A stem cell found in adult neural tissue that can give rise to [neurons](#) and glial (supporting) cells. Examples of glial cells include [astrocytes](#) and [oligodendrocytes](#)

**Neurons**—Nerve cells, the principal functional units of the nervous system. A neuron consists of a cell body and its processes—an axon and one or more dendrites. Neurons transmit information to other neurons or cells by releasing neurotransmitters at synapses

**Oligodendrocyte**—A supporting cell that provides insulation to nerve cells by forming a myelin sheath (a fatty layer) around axons

**Parthenogenesis**—The artificial activation of an egg in the absence of a sperm; the egg begins to divide as if it has been [fertilized](#)

**Passage**—In cell culture, the process in which cells are disassociated, washed, and seeded into new culture vessels after a round of cell growth and [proliferation](#). The number of passages a line of cultured cells has gone through is an indication of its age and expected stability

**Pluripotent**—Having the ability to give rise to all of the various cell types of the body. Pluripotent cells cannot make extra-embryonic tissues such as the amnion, chorion, and other components of the placenta. Scientists demonstrate pluripotency by providing evidence of stable developmental potential, even after prolonged culture, to form derivatives of all three embryonic [germ layers](#) from the progeny of a single cell and to generate a [teratoma](#) after injection into an immunosuppressed mouse

**Polar Body**—A polar body is a structure produced when an early egg cell, or oogonium, undergoes [meiosis](#). In the first meiosis, the oogonium divides its [chromosomes](#) evenly between the two cells but divides its cytoplasm unequally. One cell retains most of the cytoplasm, while the other gets almost none, leaving it very small. This smaller cell is called the first polar body. The first polar body usually degenerates. The ovum, or larger cell, then divides again, producing a second polar body with half the amount of chromosomes but almost no cytoplasm. The second polar body splits off and remains adjacent to the large cell, or oocyte, until it (the second polar body) degenerates. Only one large functional oocyte, or egg, is produced at the end of meiosis.

**Preimplantation**—With regard to an [embryo](#), preimplantation means that the embryo has not yet implanted in the wall of the uterus. [Human embryonic stem cells](#) are derived from preimplantation-stage embryos fertilized outside a woman's body (*in vitro*).

**Proliferation**—Expansion of the number of cells by the continuous division of single cells into two identical daughter cells.

**Regenerative medicine**—A field of medicine devoted to treatments in which stem cells are induced to [differentiate](#) into the specific cell type required to repair damaged or destroyed cell populations or tissues. (See also [cell-based therapies](#))

**Reproductive cloning**—The process of using [somatic cell nuclear transfer \(SCNT\)](#) to produce a normal, full grown organism (e.g., animal) genetically identical to the organism (animal) that donated the somatic cell nucleus. In mammals, this would require implanting the resulting [embryo](#) in a uterus where it would undergo normal development to become a live independent being. The first animal to be created by reproductive cloning was Dolly the sheep, born at the Roslin Institute in Scotland in 1996. See also [Somatic cell nuclear transfer \(SCNT\)](#).

**Signals**—Internal and external factors that control changes in cell structure and function. They can be chemical or physical in nature.

**Somatic cell**—Any body cell other than gametes (egg or sperm); sometimes referred to as "adult" cells. See also [Gamete](#)

**Somatic cell nuclear transfer (SCNT)**—A technique that combines an [enucleated](#) egg and the nucleus of a [somatic cell](#) to make an embryo. SCNT can be used for therapeutic or reproductive purposes, but the initial stage that combines an enucleated egg and a somatic cell nucleus is the same. See also [therapeutic cloning](#) and [reproductive cloning](#)

**Somatic (adult) stem cells**—A relatively rare undifferentiated cell found in many organs and differentiated tissues with a limited capacity for both self renewal (in the laboratory) and differentiation. Such cells vary in their differentiation capacity, but it is usually limited to cell types in the organ of origin. This is an active area of investigation

**Stem cells**—Cells with the ability to divide for indefinite periods in culture and to give rise to specialized cells

**Stromal cells**—Connective tissue cells found in virtually every organ. In bone marrow, stromal cells support blood formation

**Subculturing**—Transferring cultured cells, with or without dilution, from one culture vessel to another

**Surface markers**—Proteins on the outside surface of a cell that are unique to certain cell types and that can be visualized using antibodies or other detection methods

**Telomere**— The end of a chromosome, associated with a characteristic DNA sequence that is replicated in a special way. A telomere counteracts the tendency of the chromosome to shorten with each round of replication

**Teratoma**—A multi-layered benign tumor that grows from pluripotent cells injected into mice with a dysfunctional immune system. Scientists test whether they have established a [human embryonic stem cell \(hESC\)](#) line by injecting putative

stem cells into such mice and verifying that the resulting teratomas contain cells derived from all three embryonic [germ layers](#)

**Tetraploid complementation assay**—An assay that can be used to test a stem cell's potency. Scientists studying mouse chimeras (mixing cells of two different animals) noted that fusing two 8-cell embryos produces cells with 4 sets of chromosomes (tetraploid cells) that are biased toward developing into extra-embryonic tissues such as the placenta. The tetraploid cells do not generate the embryo itself; the embryo proper develops from injected [diploid](#) stem cells. This tendency has been exploited to test the potency of a stem cell. Scientists begin with a tetraploid embryo. Next, they inject the stem cells to be tested. If the injected cells are pluripotent, then an embryo develops. If no embryo develops, or if the resultant embryo cannot survive until birth, the scientists conclude that the cells were not truly [pluripotent](#)

**Therapeutic cloning**—The process of using [somatic cell nuclear transfer \(SCNT\)](#) to produce cells that exactly match a patient. By combining a patient's [somatic cell](#) nucleus and an [enucleated](#) egg, a scientist may harvest [embryonic stem cells](#) from the resulting [embryo](#) that can be used to generate tissues that match a patient's body. This means the tissues created are unlikely to be rejected by the patient's immune system. See also [Somatic cell nuclear transfer \(SCNT\)](#)

**Totipotent**—Having the ability to give rise to all the cell types of the body plus all of the cell types that make up the extraembryonic tissues such as the placenta. (See also [Pluripotent](#) and [Multipotent](#))

**Transdifferentiation**—The process by which stem cells from one tissue [differentiate](#) into cells of another tissue

**Trophectoderm**—The outer layer of the preimplantation [embryo](#) in mice. It contains [trophoblast](#) cells

**Trophoblast**—The outer cell layer of the [blastocyst](#). It is responsible for implantation and develops into the extraembryonic tissues, including the placenta, and controls the exchange of oxygen and metabolites between mother and [embryo](#)

**Umbilical cord blood stem cells**—Stem cells collected from the umbilical cord at birth that can produce all of the blood cells in the body (hematopoietic). Cord blood is currently used to treat patients who have undergone chemotherapy to destroy their bone marrow due to cancer or other blood-related disorders

**Undifferentiated**—A cell that has not yet developed into a specialized cell type



## APPENDIX 3

**TABLE OF CLONING TIMELINE**

<b>YEAR</b>	<b>SCIENTIFIC BREAKTHROUGHS</b>
1838	Cell Theory, Schleiden & Schwann (Germany)
1882	Mitosis, Walther Flemming (Germany)
1887	Chromosomes, Theodor Boveri (Germany)
1902	Chromosomes linked to heredity, T.Boveri (Germany) & W.Sutton (USA)
1902	Salamander clones by embryo splitting, Hans Spemann (Germany)
1938	“Fantastical experiment” proposed, later known as SCNT, Hans Spemann (Germany)
1950s	Experiments with bone marrow
1952	Tadpoles cloned by SCNT or ESCs, Briggs & T.J.King, Indiana University (USA)
1962	Frogs cloned by SCNT from adult cells, John Gurdon, Oxford (UK)
1972	Recombinant DNA, Paul Berg, Stanford, California (USA)
1973	First transgenic organism, E. coli carrying frog gene, S.Cohen & H.Boyer UCSF, California (USA)
1981	Production of ESCs from mouse embryo
1984	First mammal cloned, a sheep from ESCs, Steen Willadsen, Roslin Institute (Scotland)
1986	First cow cloned, Steen Willadsen, Roslin Institute (Scotland)
1995	Sheep clones from differentiated ESCs, Megan & Morag, Roslin Institute (Scotland)
1996	Cloning of Dolly by SCNT from adult cell, Ian Wilmut, Roslin Institute (Scotland)
1997	Transgenic sheep, Roslin Institute (Scotland)
1998	Isolation of human ESC, James Thomson, Wisconsin (USA)
1998	Mice cloned, NT Yanagimachi & Wakayama, University of Hawaii (USA)
1999	Transgenic goats, Tufts University (USA)
2000	Rhesus monkey cloned by embryo splitting, Oregon (USA)

2000	Pigs cloned by SCNT from adult cells, PPL Therapeutics, Virginia (USA)
2001	Gaur (endangered ox) cloned by SCNT, Advanced Cell Technology (USA)
2001	Mouflon (endangered sheep) cloned by SCNT (Italy)
2002	Rabbits cloned by SCNT from adult cell, France National Ag Institute (France)
2002	Goats cloned by SCNT from adult cell, Nexia Biotech (Canada)
2003	Banteng (endangered cow) cloned by SCNT, Advanced Cell Technology (USA)
2003	Rat cloned by SCNT from adult cell, France National Ag Institute (France)
2003	Mule cloned by SCNT from foetal cells, University of Idaho (USA)
2006	IPS using mouse skin cells, Yamanaka & Takahashi, University of Kyoto ( Japan)
2007	IPS using human skin cells, Thomson (USA) & Yamanaka ( Japan)
Current	Cybrids, University of Newcastle and Kings College London (UK)

Adapted from McGee G & Caplan A, *The Human Cloning Debate*, Berkeley Hills Books, Berkeley, 2004 at 17-18

## APPENDIX 4

### BLASTOCYST

A blastocyst is a microscopic group of cells that is small enough to fit into Roosevelt's eye on the face of a U.S. dime.

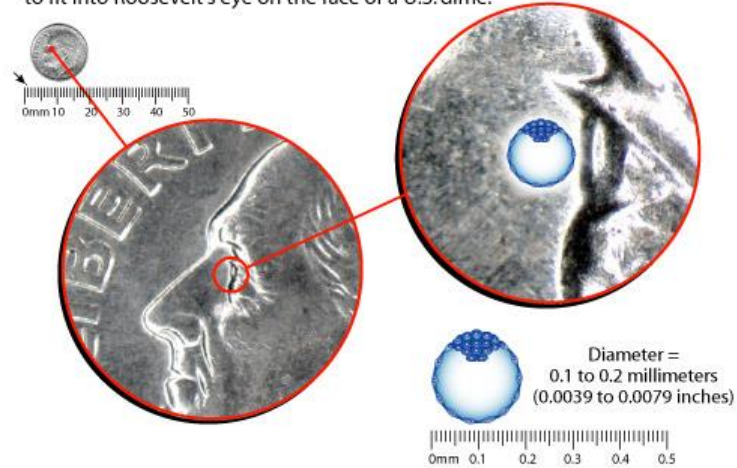


Illustration by [Cell Imaging Core](#) of the Center for Reproductive Sciences.

Figure 1: The size of a blastocyst (reprinted with permission from University of Kansas medical center, <http://www.kumc.edu/stemcell/images.html>)

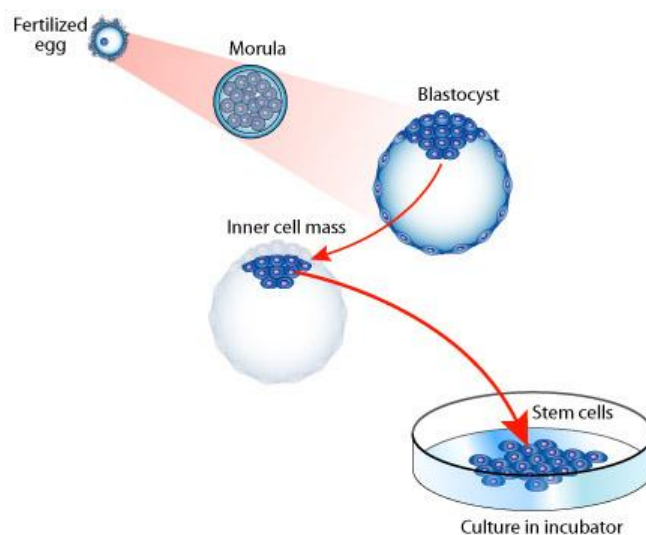


Illustration by [Cell Imaging Core](#) of the Center for Reproductive Sciences.

Figure 2: Harvesting and culturing stem cells (reprinted with permission from University of Kansas Medical Center, <http://www.kumc.edu/stemcell/images.html>)

## APPENDIX 5

**TABLE OF THE HISTORY OF REGULATION OF RESEARCH  
INVOLVING HUMAN EMBRYOS IN AUSTRALIA**

	<b>Report/ Legislation/ Guidelines</b>
1980s, 1990s	<ul style="list-style-type: none"> <li>• Legislation on Assisted Reproductive Technique (ART) in three states: Victoria, South Australia, Western Australia</li> <li>• National Guidelines: <i>National Statement, ART guidelines</i></li> </ul>
1998	Australian Health Ethics Committee of the National Health Medical Research Council, <i>Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings</i> (1998) (AHEC Report)
2001	House of Representatives Standing Committee on Legal and Constitutional Affairs, <i>Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research</i> (2001) Canberra (Andrews Report)
2002	National legislation passed: <i>Prohibition of Human Cloning Act 2002 (PHC Act 2002)</i> and <i>Research Involving Embryos Act 2002 (RIHE Act 2002)</i>
2003	State and territory legislation passed in all states and one territory
2005	Legislation review of <i>Prohibition of Human Cloning Act 2002</i> and <i>Research Involving Embryos Act 2002</i> (Lockhart Report)
2006	National legislation amended: <i>Prohibition of Human Cloning for Reproduction and the</i>

	<i>Regulation of Human Embryo Research Amendment Act 2006 (Amendment Act 2006)</i>
2007	Revised national guidelines: <i>National Statement, ART Guidelines and Objective Criteria</i>
2007-2009	State and territory legislation passed in most states and in one territory
2011	Report of the Independent Review of the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> and <i>Research Involving Human Embryos Act 2002</i> (Heerey Report)

## APPENDIX 6

### STATE/ TERRITORY LEGISLATION ON RESEARCH INVOLVING HUMAN EMBRYOS IN AUSTRALIA

State/ Territory	Passed state legislation?	Act
Victoria	Yes	<i>Infertility Amendment Act 2007</i>
Queensland	Yes	<i>Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007</i>
New South Wales	Yes	<i>Human Cloning and Other Prohibited Practices Amendment Act 2007</i>
Tasmania	Yes	<i>Human Cloning and Other Prohibited Practices Amendment Act 2007</i>
Western Australia	Bill rejected	2007
ACT	Yes	<i>Human Cloning and Embryo Research Amendment Act 2008</i>
South Australia	Yes	<i>Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research Involving Human Embryos) Act 2009</i>
Northern Territory	No	-

## APPENDIX 7

### THE MALAYSIAN GUIDELINES ON STEM CELL RESEARCH

(available at

<<http://www.crc.gov.my/guidelines/pdf/B/MALAYSIAN%20GUIDELINES%20FOR%20STEM%20CELL%20RESEARCH%20AND%20THERAPY%202009%20.pdf>>)

1. The Ministry of Health will undertake to encourage and promote stem cell research in Malaysia.
2. All stem cell research and applications must be reviewed by the respective Institutional Review Board (IRB) and/or the Institutional Ethics Committee (IEB) for approval to ensure ethical research and use of stem cells. The IRB and IEC must strictly adhere to the National Guidelines for Stem Cell Research and Therapy.
3. A copy of all research proposals must be submitted to the National Stem Cell Research and Ethics Sub-Committee which shall retain the rights to review any research proposal as and when required.
4. All experiments and clinical trials involving stem cells must be based on a solid foundation of basic scientific and animal experimentation and carried out with the highest medical and ethical standards.
5. Research on human adult stem cells is allowed.
6. Research on stem cells derived from foetal tissues from legally performed termination of pregnancy is allowed.
7. Research on non-human stem cells is allowed.
8. Use of embryonic stem cells lines for research purposes is allowed.
9. Research on embryonic stem cells derived from surplus embryos is allowed. (Please refer to the *Keputusan Muzakarah Jawatankuasa Fatwa MajlisKebangsaan Bagi Hal Ehwal Agama Islam Malaysia berkaitan Pengklonan dan ART* dated 22 February 2005)
10. The creation of human embryos by any means including but not limited to assisted reproductive technology (ART) or somatic cell nuclear transfer (SCNT) specifically for the purpose of scientific research is prohibited.
11. To facilitate autonomous choice and avoid conflict of interest, decisions related to the production of embryos for infertility treatment should be free of the influence of investigators who propose to derive or use hES cells in research. Whenever it is practicable, the attending physician responsible for the infertility treatment and the investigator deriving or proposing to use hES cells should not be the same person.

12. No cash or in-kind payment may be provided for donating blastocysts in excess of clinical need for research purposes.

13. Consent for blastocyst donation should be obtained from each donor at the time of donation. Donors who have given prior indication of their intent to donate for research any excess blastocysts that remain after clinical care should nonetheless give informed consent again when any specific research is being considered. Donors should be informed that they retain the right to withdraw consent until the blastocysts are actually used in cell line derivation.

14. In the context of donation of gametes or blastocysts for human embryonic stem(hES)cell research, the informed consent process should include the following information:-

- (a) A statement that the blastocyst or gametes will be used to derive hES cells for research that may include research on human transplantation.
- (b) A statement that the donation is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of autologous donation.
- (c) A statement as to whether the identities of the donors will be readily ascertainable to those who derive or work with the resulting hES cell lines.
- (d) If the identities of the donors are retained (even if coded), a statement as to whether donors wish to be contacted in the future to receive information obtained through studies of the cell lines.
- (e) An assurance that participants in research projects will follow applicable and appropriate best practices for donation, procurement, culture, and storage of cells and tissues to ensure, in particular, the traceability of the stem cells. (Traceable information, however, must be secured to ensure confidentiality)
- (f) A statement that derived hES cells and/or cells lines might be kept for many years.
- (g) A statement that the research is not intended to provide direct medical benefit to the donor(s) except in the case of autologous donation.
- (h) A statement that embryos will be destroyed in the process of deriving hES cells.
- (i) A statement that neither consenting nor refusing to donate embryos for research will affect the quality of any future care provided to potential donors.
- (j) A statement of risks involved to the donor.

15. Research that should not be permitted at this time:

- (a) Research involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first.
- (b) Research in which HES cells are introduced into non-human primate blastocyst or in which any ES cells are introduced into human blastocysts.
- (c) No animal into which HES cells have been introduced at any stage of development should be allowed to breed.
- (d) Fusion of human stem cell or other cells of pluripotent nature with cells of non-human origin, shall not be permitted to develop beyond 14 days, or until the formation of the primitive streak begins, whichever occurs first.



16. Laboratory requirements:

- (a) Laboratories conducting stem cell research shall conform to required guidelines for good laboratory practices.
- (b) All laboratories conducting stem cell research for the purpose of clinical trials shall be GMP compliant as required by the National Pharmaceutical Control Bureau (NPCB).
- (c) All laboratories producing stem cells or tissue products for commercial/manufacturing purposes shall be certified as GMP compliant by the NPCB.

17. All imported stem cells/tissue products for use in clinical trials and therapy shall be GMP certified and registered by the NPCB.

18. Procurement, management, storage and disposal of stem cells and tissues used in research and clinical trials must be in accordance with the national guidelines.

19. Therapeutic outcomes, adverse effects and tissue integration shall be documented or reported to the National Stem Cell Research and Ethics Subcommittee.

## **APPENDIX 8**

### **FATWA ON THERAPEUTIC CLONING AND STEM CELL RESEARCH (ENGLISH TRANSLATION)**

Reproduced from the Malaysian E-Fatwa website:

<http://translate.google.com.au/translate?hl=en&sl=ms&tl=en&u=http%3A%2F%2Fwww.e-fatwa.gov.my%2F>

The 67th Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 22nd February 2005 has discussed the ruling on therapeutic cloning and stem cell research. The Committee has decided that:

1. Therapeutic cloning for medical treatment, for instance to create certain cells or to replace damaged organ is permissible. The act is permitted provided that the Syarie precautions are considered.
2. Using frozen embryo or extra embryo in vitro fertilization process is permissible for research purpose. However, permission must be granted from the married couple who are under treatment. The research on the embryo must be done before the embryo reach the calaqa stage (blastocyst).