# NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH

## SUBMISSION TO SECOND CONSULTATION

## BY


## CENTRE FOR LAW AND GENETICS

## UNIVERSITIES OF TASMANIA AND MELBOURNE


## GENERAL COMMENTS

1. Overall, the second consultation draft of the *National Statement on Ethical Conduct in Human Research* (the *Statement*) is a sound document to serve as a basis for further revision and improvement. It is noted that it preserves much of the 1999 *Statement,* which has been generally well received by the research community. The new draft *Statement* is a much longer document that the 1999 *Statement*. In part, this reflects the increasing complexity of the issues associated with ethical review, which are reflected in the recommendations in the final report of the inquiry into the protection of human genetic information by the Australian Law Reform Commission and Australian Health Ethics Committee: *Genes and Ingenuity, Report No.96* released in 2003 (the ALRC/AHEC Report).

However, the increased size of the document is also perhaps a result of the new structure of the *Statement*. The use of headings to segregate the ethical principles leads to some repetition. The sentence structure also tends to be somewhat convoluted in places and lacks the crispness of the original Statement. Key principles underlying the statement including beneficence, justice and respect are clearly of fundamental importance in this area. In many instances, however, these principles are overused and also misused in the current draft as a result of what appears to be their somewhat mechanical application as headings to text without due consideration to the text's content.

The introductory remarks at the start of each chapter are useful, but at times this commentary overflows into the guidelines themselves. There are many instances where the guidelines are more descriptive or illustrative than guiding. This may well create problems for both HRECs and researchers in fully understanding the nature of their obligations. This draft would benefit from careful editing to reduce overlap and clarify the distinction between commentary and guidance. The guidelines for assessing risk in paragraphs 2.1.1-2.1.7 provide a useful model for re-structuring the remainder of the guidelines (once modified as suggested below). They provide clear direction to researchers and HRECs.

Generally, the second consultation draft will benefit from some pruning and considerable editing. It is hoped that this submission will assist in this process. If clarification is required we will be very happy to provide it.

2. Amongst the new chapters in the draft *Statement,* the chapters 'Risk' (2.1), 'Quality of Methods' (3.1), 'Databanks' (3.3), 'Aboriginal and Torres Strait Islanders' (4.7), 'Peoples in Other Countries' (4.8), 'Institutional Responsibility' (5.1) 'Minimising Duplication of Ethical Review' (5.3) and 'Accountability' (5.7) are particularly welcome inclusions. However, we find the chapter on 'Human Stem Cells' to be problematic. The chapter on 'Women who are Pregnant and the Fetus' requires revisions, as does the chapter on 'People Who May Be Involved in Illegal Activities'. These chapters address new areas and completion of ongoing work in research ethics and, importantly, an effort to be more inclusive of social science and humanities research. One of the concerns that has been expressed in relation to the 1999 *Statement* is that it focuses too much on biomedical research.

3. The categorisation of risk into more than low risk; no more than low risk; and, research that can be exempted from review, should assist the process of ethical review in two ways. First, it may assist HRECs to better handle their workload and to enable them to focus on particular types of research, and, secondly, increased consistency with international standards.

4. The inclusion of references to research governance in the Preamble and in Section 5, particularly, Chapter 5.7 are commendable. These parts of the *Statement* address the responsibilities of institutions and clarify the responsibilities of the institutions and HRECs. These parts go a long way in addressing the issues raised by HRECs of unreasonable expectations of them with respect to monitoring of research and assessing conflicts of interest, as examples.

5. The new draft *Statement* continues to use the set headings of 'Research Merit and Integrity'; 'Justice'; 'Beneficence'; and 'Respect'. These headings should be deleted and replaced with more appropriate headings referring to the actual material in the sub-section of the chapter. As will be seen from the specific comments below, in many cases, the use of these Headings is artificial and stilted. They are not entirely consistent. For example, at page 33 a heading entitled 'Monitoring of Approved Clinical Research' has been used. This is a correct usage of a sub-heading as it reflects the content of the material in the sub-section. It also assists the reader by directing them to the appropriate section of the material define the guidelines they may require.

6. The choice of subheadings is also problematic because it reflects a historically accepted list, albeit rigidly applied. We suggest that the new *Statement* must recognise new and emerging principles. We suggest that the principles 'Dignity', 'Solidarity' and 'Benefit-sharing' should be expressly referred to as these are increasingly recognised as keystone principles in contemporary ethical discourse, as illustrated by the UNESCO *Universal Declaration of Bioethics and Human Rights* 2005.

7. The consent guidelines with respect to different types of research are generally contained under the sub-heading 'Respect'. Consent issues in research are the core, fundamental inquiry for the researcher and the HREC. The consent process is also at the core of the ethical relationship between researcher and participant. These are pivotal considerations for HRECs and are worthy of more prioritised listing in the Chapters.

8. The waiver of consent provisions have been hidden in the current draft. The ALRC/AHEC Report recognises the potential controversiality in the application of these provisions and called for greater transparency in application and accountability. These provisions must be given separate and prominent treatment, with careful cross-referencing to those types of research in which these are core considerations.

## SPECIFIC COMMENTS

### Section 1: Values and Principles of Ethical Conduct

Page 5

The heading 'Research Merit and Integrity' conflates two principles. The 1999 *Statement* listed integrity of the researcher as the first principle of ethical conduct (1.1). There is justification for retaining this value in a separate heading. As well as the researcher, the integrity of all those involved in the research project is an essential aspect of the research endeavour. Research merit is equally important. However, the principle of research merit focuses on the project rather than the research personnel. Research merit highlights the standards of design, justification for research, methodology and standards (including knowledge of literature, appropriate facilities and qualified researchers). These issues are closely related but sufficiently separate to deserve separate treatment. This should be addressed also elsewhere in the new *Statement* where these words 'Research Merit and Integrity' appear together (eg at 1.8)

It is noted that the current sub-headings 1.1 and 1.2 already deal with research merit and integrity independently and respectively.

Page 6. Heading: Beneficence

Paragraphs 1.5 -1.7 do not deal with doing good (beneficence) but rather, avoiding the risks of harm or discomfort to participants (arguably, non-maleficence). It is noted that these three sub-sections are, in fact, an expansion of the 1999 *Statement* Principle 1.3. However, the heading does not reflect the content of these paragraphs.

In a previous submission it was noted that these values/principles are important in the research endeavour. However, as noted above, dignity, solidarity and benefit-sharing are also vitally important ethical principles in research involving humans. In particular, the principle of dignity arguably underlies the guidelines in Chapters 4.4 and 4.5. The 1999 *Statement* made reference to this important principle, not included in the current draft, stating that:

> each research protocol must be designed to ensure that respect for the *dignity* (emphasis added) and well being of the participants take precedence over the expected benefits to knowledge (Principle 1.4).

There is an intrinsic relationship between respect and dignity. Similarly, although benefit-sharing may be considered to be a developing principle, not yet recognised in mainstream ethical thinking, there are already places in the current Draft that express,

or at least imply, the idea of community benefit (see for example, 4.8.13, p76). We suggest that the principle of benefit-sharing should expressly recognised in the Statement.

**Section 2: Themes in Ethical Review: Risk and Consent**

It is proposed that this Section should include a new Chapter entitled 'Research Governance and Accountability'. The ALRC/AHEC Report recommended that consideration be given to increasing the enforceability of the *Statement* (Rec 14.1) and to strengthening the review procedures of HRECs (Rec 17-1). The inclusion in this Consultation Draft of references to research governance in the Preamble, to institutional responsibility and accountability in Chapter 5 go some way towards meeting the spirit and intention of Recommendation 17, but could go further. This should be addressed in the opening part of the *Statement*, after identification of values and principles of ethical conduct.

It is recommended that the new Chapter 2.1 Research Governance and Accountability, include the current:

- Research Governance (5.1.1 and 5.1.2)
- Continuing Oversight of Review Procedures (5.1.10-5.1.14)
- Guidelines for Accountability (5.7.1-5.7.6)
- Heading to Chapter 5.7 Accountability – Introduction
- Heading, Research Governance (page vi)

It is strongly suggested that this revised chapter include references to the various Codes of Professional Conduct, relevant legislation and institutional policy statements. The revised *Statement* attempts to recognise that it is not the sole source of ethical guidance. The concept of good research governance and accountability clearly extends beyond the researcher and the HREC to embrace the institution's local, national and international responsibilities. Many researchers are also members of professional associations that have established Codes of Professional Practice that are often accompanied by procedures for complaints and discipline. Similarly, academic researchers are subject to University Rules and Procedures. The *Statement* does mention the influential Joint NHMRC/AVCC *Australian Code for Responsible Conduct of Research*. The *Statement* should acknowledge, especially in the governance chapter, these other ways in which the conduct and culture of ethical research is maintained in this country.

It is proposed that Chapter 2.1 'Risk', be renumbered as 2.2 and Chapter 2.2 'Consent' be renumbered 2.3.

*Chapter 2.1 (renumbered as 2.2): Risk*

The conduct of research in Australia is generally of a high standard. There are few reported instances of research impropriety and also few cases of harm. Might some contextual introduction be included setting out this historical record? Without some context the inclusion of this new chapter may convey to the public a sense of 'risk' in human research, when, in fact, the history of impropriety is minimal. Such a chapter

would include some but not all of the text under the headings ‘Minimising Risk’ and ‘Benefits and Risks’. These headings are misleading with their current text.

Paragraph 2.1.2, renumber sub-paragraph (c) as (b). This sub-paragraph is also involved with the process of identifying risks.

Insert new sub-paragraph (b), ‘Assessing the Risk’. Apart from risk identification, risk assessment is a critical step and is in fact, referred to in 2.1.3.

Sub-Paragraph (b) should be renumbered as (d), (d) should be renumbered as (e), and (e) should be renumbered as (f).

Insert new sub-paragraph (f) Balancing and assessing the risk and benefits of the project. This is the key step and is referred to in the paragraph headings of ‘Minimising Risks’ and ‘Benefits and Risks’ on page 10.

Paragraph 2.1.3. This guideline should be revised. First of all, the guideline should have two separate points, the first referring to the ethical duty of researchers to accurately assess the risk and to include whatever basis upon which their calculation of risk has been identified and assessed. The second and quite separate consideration is the cautionary remark for each HREC to be realistic in their identification and assessment of the risks. Arguably, this is not a guideline but a general point, which should be included in the introductory section entitled ‘Quantifying Risk’ at pages 9-10.

Paragraph 2.1.5. This is an important guideline directing each HREC to take account of participants’ perspective on risk. Risk perception is a component of risk identification and assessment. The words ‘and assess the significance of risks in research against the experience and opinions of participants’ are, arguably, repetitive and do not add to the guideline.

Paragraph 2.1.6. This guideline could be revised and edited. Why should voluntary willingness or ‘readiness’ be judged differently when a direct benefit is involved. Is the responsibility of HRECs not the same in all cases, namely, that HRECs should examine all the circumstances of consent to participate in projects where there is more than low risk (using the words of Chapter 5) including the question of any benefits derived by the participants for the families.

This paragraph does not make any reference to *surrogate* participant research. It is not clear whether this was a deliberate omission.

Paragraph 2.1.7. It is noted that the wording ‘as long as is ethically achievable’ does not appear consistent with the language used in Chapter 5.

It is suggested that the current paragraphs 5.1.3-5.1.9 ‘Processes for Ethical Review’; Paragraphs 5.1.5-5.1.20 ‘Research Involving Lower than Lower Risk’; and, a reference to, or if not, a transfer to Paragraph 5.1.9. Inclusion of these paragraphs in this Section would mean that the HREC has a consolidated section, ‘Risk Identification, Risk Assessment’, for consideration of risk and its dependence on the

level or type of research. This will aid the HREC through new and challenging guidelines.

There should be a cross reference to Paragraph 2.2.6. That, in turn, should be cross-referenced to the paragraphs of this Chapter.

*Chapter 2.2 (renumbered as 2.3): Consent*

This is an important Chapter setting out the primary and key responsibility for each HRECs. Many of the guidelines are too long and could benefit from some editing. The length of the chapter may be challenging to HRECs and the lack of distinction between commentary and guidelines is particularly problematic here. The distinction between the three tiers of consent (specific, extended and unspecified) is critical in some areas of research, particularly genetic databanking. This distinction needs to be highlighted by separating out the terms from the dense body of text.

Much research is now being conducted in an increasingly commercialised setting. Government, as well as universities and companies, are promoting research with commercial aims. It is proposed that a clear statement be included in this chapter that commercial research should be clearly notified to participants. There may be a danger of loss of public confidence if conflicts of interest with commercial aims and interests are not declared.

Paragraph 2.2.4. Delete the words 'the process of communicating such information should not become a matter of merely satisfying a formal requirement' and substitute 'the consent process is not merely formal but aims to promote an understanding between …. research participants and to provide an opportunity to discuss all the aspects of the research project'.

Paragraph 2.2.5. Delete the first sentence 'Where the research project…who are valuable' substitute 'in long running projects participants should [continue with sentence 2].'

This is an important distinction in relation to once off research and is worthy of a separate sub-heading. It is not really a part of general requirement rather, an example of specific circumstances for variations in the consent process.

Paragraphs 2.2.8 and 2.2.9. Payment and Reimbursement is a continuing contentious and unresolved issue. These are key guidelines and deserve a separate sub-heading. It is essential that they are clearly separated as they mark a major shift in thinking and culture from the 1999 *Statement*. This should be highlighted. Moreover, the distinction between payment and benefit-sharing (see paragraph 5 in our general comments, above) should be adumbrated at this point.

Paragraph 2.2.8. Reword. Payments to research participants are unethical if they affect the voluntariness of consent or induce participation in undue risks.

Paragraph 2.2.9 requires editing.

Paragraph 2.2.11. This appears to overlap and repeat the summary guideline of Paragraph 2.2.6.

Paragraph 2.2.13-2.2.15 'Consent to Future Use of Date and Tissue in Research' should be included in Chapters 3.3 and 3.6 respectively. These are not general but quite specific consent provisions deserving of treatment in the appropriate chapter.

Paragraph 2.2.13. The final two sentences are separate ideas and should be the subject of separate guidelines, namely:

- Extended consent and including permission to enter the data into the databank
- The restrictions in the use of participant's data and access

Paragraph 2.2.14. Again, the final two sentences beginning 'Research proposals that…[to]…given by participants' are both separate ideas dealing with the approval process by HRECs and a separate record to the participants. These must be treated separately. Overall, this current paragraph requires editing.

Paragraph 2.2.15. This guideline appears to confuse three separate ideas. Namely, additional data entered into the databank; additional consent (either unspecified or extended, using the language of the *Statement*) and whether the consent is required or not (surely the use of the word 'may' as a conjunctive is inaccurate. This guideline should be revised. Generally, the new draft *Statement* does not clearly distinguish between three circumstances as follows:

- a formal established databank (including linkages of existing data) where original consent is obtained including consent for future use of data.
- a specific collection of data for a specific purpose subject to a limited (not 'extended') consent using the language of the Draft *Statement*.
- existing data collections, often collected for a purpose, that are now the subject of applications for a different use.

There is a tendency in these consent provisions and the critical waiver provisions to conflate these different circumstances. Similar comments apply to the chapter on databanks (3.3).

Paragraph 2.2.16. The original wording of the 1999 *Statement* Principle 1.8 is preferable. The second sentence is vague. Should it not read: 'Researchers must do all that they can to ensure that people who decline to participate will suffer no disadvantage'?

Paragraph 2.2.17. The reference at the end of the paragraph should be '2.2.3 (f)'.

Paragraph 2.2.18. There is a conflation of two separate ideas. The first is the *exceptional* circumstances (emphasis added) in which consent may be waived and the second relates to those fields of research where is more common not to proceed with consent, e.g. epidemiological consent. These should be clearly separated and stated as such. See the comments above in relation to paragraph 2.2.15.

Paragraph 2.2.19. Again, there is a conflation of consent and waiver. These are quite independent processes and should be separated.

Paragraph 2.2.21. The words 'in thinking about' are vague and should be deleted and the paragraph revised to read 'in application for waiver of consent by a researcher, an HREC must consider the following'. The equivalent of Paragraph 2.2.21(f) in the 1999 *Statement* was deficient as it did not explain how the possibility of commercial exploitation could impact on an HREC's decision as to whether or not to waive consent. There is a clear opportunity to clarify this deficiency by explaining that the norm should be open disclosure of commercial intention. The research findings of our group suggest that this will not impinge negatively on research participation as people value openness.

Paragraph 2.2.22 largely repeats the previous paragraph. The two could be combined.

Paragraph 2.2.23. This is a critical paragraph dealing with the ALRC/AHEC Report, Recommendation 15-3. This Recommendation aimed to improve the interpretation of the waiver of consent provisions in the *Statement* and the HREC decision-making. We believe that it is important that not only the institution but the AHEC itself should be aware of any waiver. The Annual Report to AHEC should include information about any waivers. This will enable an independent and reliable record to be kept of waivers and for any follow-up to be carried out.

**Section 3: Ethical Considerations Specific to Research Methods or Fields**

*Chapter 3.1: Qualitative Methods*

Heading: Research Merit and Integrity

It is noted that none of the paragraphs below refer to the integrity of the researcher. Consistent with submissions in relation to Section 1 above, we believe this should be explicitly addressed as a distinct consideration.

Paragraphs 3.1.2, 3.1.3 and 3.1.4 are not currently phrased in the form of directive guidelines but are descriptive only. They should be transferred into the Introduction.

Paragraph 3.1.6. This paragraph requires considerable re-editing. As with paragraphs 3.1.2-4, it is not a guideline but is a characteristic descriptor of qualitative research and should be included in the Introduction.

Paragraph 3.1.7. This paragraph does not deal with justice. This is an inaccurate sub-heading. It is part of consideration of research merit and should be included after 3.1.4 (renumbered).

Heading: Beneficence

The four paragraphs deal with issues of confidentiality and not beneficence. The sub-heading is inaccurate.

Paragraph 3.1.10. This is a paragraph dealing with research merit and design. In addition, the final sentence beginning 'researchers should…effects' is a separate issue and should be included in a separate paragraph.

Paragraph 3.1.11. This paragraph does not deal with beneficence but rather the responsibilities of the researchers or the research design and should be moved to the appropriate sub-heading.

Paragraph 3.1.12. This paragraph deals with the responsibilities and arguably, the 'integrity' of the researcher. It should be moved to a separate section or alternatively, included as part of research merit design.

Consent is an important aspect of qualitative methods and a number of the paragraphs advert to the special aspects of qualitative research. There should be cross-references to the Consent chapter.

*Chapter 3.2: Limited Disclosure*

Heading: Research Merit and Integrity

Paragraph 3.2.1 does not deal with research merit and integrity. Rather, the issue is the justifiable breaches of general principles of consent. This may be, arguably, an issue of justice but the heading is not helpful.

Heading: Beneficence

Paragraph 3.2.2. This does not deal with beneficence but rather risk. This is an important issue and deserves cross-referencing to the Risk sections and further clarification of the types of risk involved with limited disclosure.

Paragraph 3.2.3. This is a confusing paragraph. Generally, the paragraphs dealing with risk talk about balancing risks and benefits. This introduces a new idea of 'might corrupt' relations between community and research and research in general. This is very vague and is not clear whether this is a general comment on this type of research or a direction to the HRECs to investigate a complex issue, possibly beyond their competence.

In any case, the words 'might corrupt' are extremely vague. Note that the word 'might' should read 'may'.

Paragraph 3.2.4. This paragraph should be re-worded to ensure that there is reference to the fact that this is an exceptional circumstance. There is value in repeating the wording of 2.2.20 here as this is a major circumstance in which this paragraph will apply.

There ought to be some cross-reference in the paragraphs or in the Introduction to Chapter 4.6 dealing with illegal activities.

*Chapter 3.3: Databanks*

This is an important new chapter in the *Statement.* The chapter addresses recommendations in the ALRC/AHEC Report (Recommendations 18-1 to 18.4 and 19-1, 19-2). This chapter also addresses the developing and expanding use of databanks for research.

Introduction

The text on pp25-26 is important. Some of the paragraphs in fact, refer to important background information. It is suggested that readability could be improved with the use of additional sub-headings, such as 'Data', 'Identifiability', 'Tissue and Data', 'Banking' and 'Future Projects'.

Generally, this chapter could be substantially improved by distinguishing between three circumstances as follows:

- A formal established databank (including linkages of existing data) where original consent is obtained including consent for future use of data.
- A specific collection of data for a specific purpose subject to a limited (not 'extended' consent using the language of the Draft *Statement*).
- Existing data collections, often collected for a purpose, that are now the subject of applications for a different use.

There is a real and practical difference between proposed guidelines dealing with these circumstances.

Page 25

The new categories of 'individually identifiable'; 're-identifiable or potentially re-identifiable' and 'non-identifiable', will replace the categories of 'previous identified'; 'potentially identifiable (re-identifiable)' and 'de-identified (not re-identifiable)'. Essentially the categories cover the same territory, but the new terminology is preferable. Individually identifiable is a more accurate term than identified. Similarly, the term non-identifiable is preferable to de-identified for the reasons set out at the foot of page 25.

Page 26, second paragraph

The statement that human tissue samples may always be regarded as, in principle, potentially re-identifiable is accurate. It also reflects the fact that the value of these collections will depend significantly on the capacity of the researcher to follow up general findings with particular individuals. This is an extremely important point and is worthy of a separate sub-heading and some guidance comments. The relationship of this re-identifiability should be related to research design, privacy, obligations and storage of information.

The introductory text does not cover the general principles of confidentiality and privacy and compliance with Federal and State legislation. It is desirable that some general comment should be made to this effect.

It is also desirable that some comment is made about the use of independent intermediaries in appropriate cases to hold codes linking genetic samples or information with the identifiers (see ALRC/AHEC Report, Recommendation 16-1(b)). The linkages that are being developed from existing tissue collections are generally following this process. It is desirable that this should be the standard and some comment to that effect has been made (see comment in relation to paragraph 3.3.7).

Page 26 last paragraph of the introduction beginning 'These are ethical principles…data collections'

The responsibility of institutions to establish policies, principles and guidelines in relation to the data collections under their control is an essential guideline. This sentence is consistent with the broad recommendations of the ALRC/AHEC Report. It is not in a prominent enough position. It is worthy of inclusion under the heading, 'Responsibility of Institutions'.

Heading: Research Merit and Integrity

Paragraph 3.3.1 does not deal with either research merit or research integrity. Rather, it deals with the establishment of databank. This paragraph omits discussion on a vast array of major points such as the consent process set out in paragraphs 2.13-2.15 the use of the data in future projects, and protocols for the access to the information.

Most importantly, this paragraph deals only with the prospective establishment of a databank by researchers. It does not deal with existing sets of data, which may be the subject of application for use. Nor does it cover the circumstance of linkage of existing databanks, as is occurring in a number of states, particularly with cancer data.

Heading: Justice

Paragraph 3.3.2 includes two separate ideas, neither of which necessarily refers to justice. The treatment of participants fairly is separate from the promotion of access to the benefits of research (in itself a rather vague idea) and from the collection, storage and accessibility for future projects. These two ideas are more to do with the establishment of a databank and the given sub-heading.

Heading: Beneficence

Paragraph 3.3.3 does not deal with beneficence but rather the conditions and use of information by researchers according to the conditions of the providers. This is a critical concept and is more aspect of consent. In addition, paragraphs 2.13-2.15 should be included here subject to the comments above. A major challenge to the development of the use of databanks will be an established regime for the future use of the data.

Paragraph 3.3.4 – 3.3.7 should be included under the heading 'Confidentiality'. They are not dealing with beneficence to participants but rather the protection of information.

Paragraph 3.3.4 has two ideas: the linkage of data sets and the removal of identifiers. These should be the subject of separate paragraphs.

Paragraph 3.3.5. The duties of custodians is worthy of consideration in the introductory text (as stated above) and should be the subject of a separate sub-heading and an expansion of those duties.

Paragraph 3.3.6. This paragraph is awkward and should be revised. In substance, it does not answer the question whether the custodian should convey that information to the person concerned. This is an extremely important policy consideration that was covered under the 'Human Genetic Research' sections of the 1999 *Statement*. At least, it is matter that should be included in the Policy Statement by the institution concerned.

Paragraph 3.3.7. This paragraph covers two situations, namely the researcher and/or the data warehouse. This is a complex paragraph that is more descriptive than in the form of a guideline. The paragraph should be revised.

The statement that 'in most situations, the custodian of data will be the individual researcher' may be factually accurate, but is highly questionable. Larger databanks are less likely to be controlled by the researcher, and where larger collections are being linked, independent and proper governance arrangements are being put in place. We propose that there ought to be two separate circumstances defined:

1. Where there is a custodian (independent intermediary), and
2. Where the custodian is the researcher.

These are fundamentally different circumstances and importantly, circumstances that should be treated separately. As a consequence, these circumstances should be communicated and drawn clearly to the attention of potential participants when entering data on themselves.

Heading: Respect

The three paragraphs deal with the important issue of access, rather than respect. It is preferable that the sub-headings refer to the content of the paragraphs.

Paragraph 3.3.9. There are two separate ideas in this paragraph: first, consent, and secondly, confidentiality by the researcher. The consent of the participant is the fundamental issue in relation to databanks. It is important that the consent provisions are included as the opening guidelines. Secondly, the confidentiality sentence requires separation, expansion and revision. It is not sufficient to say that researchers should 'take every precaution to prevent data from becoming available for uses for which the participants did not consent'. This should be in mandatory form. In fact, the use of data outside of consented uses is almost certainly a breach of legislation and has serious consequences at law.

Paragraph 3.3.10. This is an extremely vague section. It is not clear to what circumstance the guideline applies. It is proposed that this should be revised.

*Chapter 3.4: Therapies and Interventions, including Clinical and Non-Clinical Trials, and Innovations*

Paragraph 3.4.3(d). The CPMP/RCH reference to 135/95 should be checked.

Heading: Justice

Paragraph 3.4.6. This paragraph does not refer to justice but rather to research methodology. Perhaps further guidance could be included about the justification for recruitment of specific groups.

Heading: Beneficence

Paragraph 3.4.7. This paragraph generally repeats the current paragraph 2.1.1 about risks and benefits. It is not clear why this requires repetition at this point.

Paragraph 3.4.8. It is noted that this paragraph uses different words than those in paragraph 2.1.3. Is there any reason for this change? Generally, consistency in words will avoid interpretation difficulties.

Paragraph 3.4.9. This paragraph goes to the issue of merit and design and should be moved.

Paragraph 3.4.10. Again, this is more appropriately moved to the research merit section.

Heading: Respect

Paragraph 3.4.12. This is a very important provision and is deserving of an appropriate sub-heading, rather than 'Respect'. The issue focuses on exaggeration or over-optimism about a trial. It should also be linked to paragraph 3.4.14 where there is a real risk of potential conflicts of interest. Both these paragraphs are dealing with the question of voluntariness and independence rather than respect.

Paragraph 3.4.15. This is an important guideline repeating, as many others, the 1999 *Statement*. It may be preferable to include a heading HREC Responsibilities and the Consideration of Clinical Trials and then group together the various paragraphs.

Heading: Monitoring of Approved Clinical Research

Paragraph 3.4.20. This paragraph deals with discontinuance of a trial rather than monitoring. It may be advisable to include a separate sub-heading to assist in readability.

Paragraph 3.4.21. A sub-heading should be included on 'Compensation'.

*Chapter 3.5: Human Genetics*

Generally, this chapter follows the 1999 *Statement* in principle with expansion of the text. The chapter is lengthy and could benefit from considerable editing. One of the major difficulties is that the headings do not assist the readability of the chapter. It may be worth considering reinstating the sequential headings used in the 1999 *Statement*.

Introduction

Line 1. Perhaps a reference to 'gene expression' could be included.

Sub-paragraph (a). Perhaps a reference to gene interaction could be included.

Sub-paragraph (c). Delete the example, it does not add to the point.

Fourth paragraph beginning 'In addition…relatives'. This could be considerably edited to 2 or 3 dot points.

Fifth paragraph at top of page 37. It is suggested that this paragraph be deleted.

Sixth paragraph on page 37. Essentially, this paragraph repeats paragraph 4 on page 36 and should be edited along with that paragraph.

Heading: Research Merit and Integrity

Paragraph 3.5.1. This is a lengthy paragraph that could be better expressed in hanging dot points. In particular, the final sentence 'where participants decide to be notified…' is an extremely important issue and deserves clear and separate treatment under a discreet heading. It should not be lost under the heading 'Research Merit and Integrity'. In fact, this issue has nothing to do with research merit but rather the central concern about conveying medically relevant information to participants. Once it is established that the information is individually identifiable or potentially re-identifiable, notifying medically relevant information does not become a question of choice but the general standard with the exception, likely to be extremely rare, where someone does *not* want to be informed.

Heading: Justice.

This heading should be replaced with the heading 'Respect' or 'Potential Harm'.

Paragraph 3.5.2 does not deal with the issue of 'Justice'.

Paragraph 3.5.3. This paragraph does not deal with 'Justice' but rather future research access. It is an extremely generally provision and does not give sufficient guidance on privacy, design, communication of the project to participants and other essential information in relation to the design of the project. More importantly, this paragraph should be reconsidered in view of the introductory comments in Chapter 3.3 Databanks, where it is stated that the information should always be considered 'potentially re-identifiable'. There is a glaring contradiction between this paragraph

and paragraph in 3.3. There is little likelihood of this information being 'non-identifiable'.

Paragraph 3.5.4 and heading Beneficence. This paragraph is really dealing with three separate ideas: research design; potential breaches of privacy; and research results. The separate ideas should be treated separately. The paragraph is also very lengthy and would be better set out in hanging dot points.

The last sentence 'this advice…clinical testing and research results' is a critical point and should be in a separate paragraph with a separate heading. 'Beneficence' is an aspect of this idea but it is not the appropriate heading.

Paragraph 3.5.5. A new paragraph (a) should be inserted, referring to compliance with rules and procedures developed by the institution. Elsewhere there is reference to the need for institution policies. Researchers, must, in the first instance, comply with their institutional rules.

Paragraph 3.5.6. This paragraph does not deal with beneficence but rather known maleficence. It may be better to include a sub-heading avoiding harm. Again, this is a lot larger paragraph that might be better expressed in dot points.

Paragraph 3.5.7. There is a conflation of two important ideas, consent and waiver. Elsewhere in this submission (see paragraphs 7 and 8 in our general comments, above) we have stressed the imperative of a transparent and separate treatment of the circumstances in which waiver of consent may be granted. Waiver should always be the exception and should be clearly separated under a separate sub-heading cross-referenced to paragraph 2.2.1 and 2.2.3. The complaints that may arise in the future about genetic research are likely to relate to inappropriate consent processes. This is particularly the case because the unique and long term characteristics of this type of research. The guidelines should ensure that the HREC clearly separates consent and waiver considerations. These are clearly separate procedures and requiring separate consideration, documentation and reporting.

Paragraph 3.5.8. This paragraph is another glaring example of internal inconsistency and contradiction in the *Statement.* This paragraph essentially states that information should only be used within the context of the 'consent originally provided'. This precludes the use of waivers of consent. This is appropriate in most circumstances. The relationship of this paragraph to the waiver provisions in Chapter 2.2 must be carefully re-examined.

Paragraph 3.5.9 (a). This sub-paragraph should be edited.

Paragraph 3.5.9 (b). There are three points in the paragraph that should be separated, namely, privacy and confidentiality (Sentence 1), information to participants (Sentence 2) and use in non-identifiable form (Sentence 3). Each of these should be separated.

Paragraph 3.5.9 (c) deals with the issue of results relating to health and the communication. This should be included as a separate sub-heading. In addition, a

guideline should be included giving some direction about what should be done in this event.

Paragraph 3.5.9 (d). This paragraph is lengthy and should be edited. The last sentence beginning 'decision…available are taken' is a separate and independent idea, which could be contained in a separate paragraph.

Paragraph 3.5.9 (e). This paragraph is most closely related to sub-paragraph (c). In addition, the disclosure issue in the second sentence should be separately dealt with. Has there been general consent in submissions to the proposition that information be given even if the research participant does not consent?

Paragraph 3.5.13. It would be useful to include a heading above this paragraph, 'Confidentiality/Privacy', to assist readability and reflect the content of the paragraph.

Paragraph 3.5.15. A heading, 'Storage', should be included to reflect the content of the paragraph. Genetic research results, by their nature, will always be stored. Once a heading such as 'Storage' is included, it becomes desirable to use the sequential flow of headings from the *Privacy Act 1988* (Cth) of 'collection, storage, access to …. etc'. Similarly, these headings should be followed in the databank section.

Paragraph 3.5.16. This is a primary guideline and should be the opening guideline in this chapter. Institutions (delete the words 'wishing to') conducting the research should have policy statements. The second part of this paragraph deals with provision of these policies and this is a separate idea, which should be included as a separate guideline.

Paragraph 3.5.17. This is a critical consideration in genetic research. Consent should be the starting point for ethical consideration. Importantly also, consent establishes the parameters to future research and contact with family or other parties. The broad range of considerations set out in the 1999 *Statement* and in paragraph 3.5.9 of this draft *Statement* should be amalgamated. It is inappropriate that this consent issue is placed at the end, almost as an afterthought.

Paragraph 3.5.18. This paragraph is dealing with results and would be more appropriately positioned close to or after paragraph 3.5.9.

The chapter on Consent includes (2.5) a guideline on 'long-running projects'. Much genetic research will be long-running and it may be appropriate to use headings reflecting this fact with cross-referencing to those provisions.

*Chapter 3.6: Human Tissue Samples*

Introduction

Perhaps some general reference to the relevant College of Pathologists' guidelines on the use of samples for research purposes should be made.

The bold paragraphs should refer to the Chapters on 'Databanks' and 'Genetic Research' as well as Section 1.

Heading: Research Merit and Integrity

Paragraph 3.6.1. The requirement for institutions to develop policies is an essential provision. There are institutions with policies. They may also have, in addition, specific policies on guidelines in relation to tissue banks. The existence of these policies is not a matter of research merit but a responsibility of institutions and researchers. The heading is not appropriate.

Paragraph 3.6.3. The heading 'Justice', is inappropriate, as the paragraph deals with confidentiality and privacy.

Heading: Beneficence

Paragraph 3.6.4 does not deal with beneficence, but rather, research, design and merit.

Paragraph 3.6.5. As in dealings with databanks and genetic research, consent in its various aspects is the central consideration. It is quite artificial to reduce it to this lower ranked paragraph number.

Paragraph 3.6.6. This is inadequate coverage of the complex and varied uses of tissues, particularly of the alternative use of tissues collected for research purposes. These procedures should be spelt out carefully. For example, an HREC may conclude that it is not appropriate for them to be used at all, or that specific consent must be sought.

It is not appropriate to say that consideration of the HREC in obtaining consent should be dependent on the possibility that the use 'may lead to harm, benefit or injustice'. The primary starting point should be consent.

Paragraph 3.6.7. As stated in relation to paragraph 3.5.7 above and for the reasons set out there, it is not appropriate to include waiver without some direction and qualification. The use of these samples for research purposes should generally be exceptional and require justification before an HREC. The way in which this and paragraph 3.6.6 are juxtaposed suggest that consent is only required where harm, benefit and justice, applies and if not, just merely apply for a waiver.

Paragraph 3.6.8. Again, the addition of the words 'or an HREC has waived the need for further consent' is inappropriate. Waiver is an exceptional circumstance and should not be balanced against consent, suggesting that there are two equal processes for the consent or waiver.

Paragraph 3.6.9. The final line 'should' should be replaced by 'must'.

Paragraph 3.6.10. The words 'should try to accommodate any reasonable wishes' are not appropriate and must be re-revised.

*Chapter 3.7: Human Stem Cells*

The provisions in this chapter generally overlap with the legislation. In addition, there is overlap with the guidelines and procedures of GTRAP, which should be referenced. It is not clear which guidelines refer to embryonic stem cells requiring legislative approval from the Licensing Committee and which refer to stem cells derived from other forms of tissue.

It may be desirable to take the relevant non-embryonic stem cell sections and include these as a sub-heading of human tissue. The general principles applying would seem to be common.

The stem cells derived from human umbilical cord or placental tissue would be better included in Chapter 4.1, or, at least these paragraphs should be cross-referred.

One member of our group was involved in the drafting of a submission by the NHMRC Licensing Committee in relation to this chapter. Attention is drawn to this submission.

**Section 4: Ethical Considerations Specific to Participants**

*Chapter 4.1: Women Who Are Pregnant and the Human Fetus*

Heading: Research Merit and Integrity

Paragraphs 4.1.1 and 4.1.3 do not deal with research merit and integrity but with non-commercialisation. This is consistent with law and ethical principles. The heading should be reconsidered.

Heading: Justice

Paragraph 4.1.4 does not deal with justice to women but rather the conscientious objection of those engaged in research projects. The heading should, therefore, be 'Conscientious Objection'.

Paragraph 4.1.5. The heading 'Beneficence' should be replaced with the heading 'Counselling and Support'.

Paragraph 4.1.6. This paragraph is complex and include three separate ideas. The third sentence beginning 'where research involves a foetus…be necessary' should be a separate guideline.

The final sentence is a cross-reference to Chapter 2.2 'Consent' and should be included in the bold paragraphs in the Introduction.

Paragraph 4.1.7. This guideline, which could benefit from editing, refers to research design and should be moved accordingly. The use of the word 'completely' does not clarify the sentence and should be deleted.

Paragraph 4.1.8 deals with risks and benefits and is more appropriately included under 'Research Design' as is Paragraph 4.1.11.

Paragraph 4.1.13 is a general point and not in the form of a guideline. It would be better included in the Introduction.

Paragraph 4.1.14 may be better dealt with in the 'Human Tissue' chapter. In any case, the succeeding paragraph 4.1.15 should logically come before.

Paragraph 4.1.19 – 4.1.22 may be better situated in the 'Human Tissue' chapter as further reference to the requirement for institutions to develop policies in relation to tissue dealing. Dealings with deceased foetuses and foetal tissue are sensitive and controversial areas and it is proper for institutions to have developed policies in this respect.

*Chapter 4.2: Children and Young People*

The headings 'Justice', 'Beneficence' and 'Respect' do not accord with the contents of the succeeding paragraphs.

Paragraph 4.2.7. This is more appropriately placed after paragraph 4.2.4. Additionally, the words 'even if it is as obvious as the fact that the child is an infant' is awkward and should be revised.

Paragraph 4.2.8. These points relate to circumstances in which consent is not required. There should be a cross-reference to the relevant revisions in the Consent Section. Additionally the end words 'of each project is enough' is awkward and should be re-worded.

Paragraph 4.2.9 and 4.2.10 should be under a heading 'Best Interest of the Child'. These are consistent with the general family law standards and should be appropriately listed.

*Chapter 4.3: People in Dependent or Unequal Relationships*

Paragraph 4.3.1. This is not a guideline but rather a statement of consent in dependent or unequal relationships to be carefully examined on a case by case basis to ensure the adequacy and voluntariness of consent.

Heading: Justice

Paragraphs 4.3.2 and 4.3.3. Both these paragraphs deal with research design and should not be included under the heading 'Justice'.

Paragraph 4.3.4. The first two sentences are cautionary remarks about minimisation of these relationships on the consent process. Their introductory components should be combined with paragraph 4.3.1 and edited. Similarly, the last sentence of paragraph 4.3.4 is unnecessarily complex and is respectively making the same point.

Paragraph 4.3.5. The words ‘such as discrimination…other disadvantage’ should be deleted as they do not add anything to the otherwise crisp guideline.

Paragraph 4.3.6. If anything this is referring to research design but it is questionable whether this is saying much more than respect people. That, in itself, is not a guideline.

Paragraph 4.3.7. This is an important idea and quite separate from respect. It is a procedural guideline suggesting independent advice. This deserves a separate and clear heading.

Paragraph 4.3.8 should be under heading ‘Confidentiality’.

*Chapter 4.4: People Highly Dependent on Medical Care*

Heading: Justice

Paragraph 4.4.2. This paragraph should be reworked. What does ‘might seem unfair’ mean? This is a paragraph simply stating that the dependent relationship does not disentitle participation but that great care should be taken in recruitment. This does not seem to be a problem in relation to justice but in relation to care and recruitment as an ethical principal requiring a separate sub-heading.

Heading: Beneficence

Paragraph 4.4.3 relates to research design rather than beneficence.

Paragraph 4.4.4. The first sentence is a clear statement requiring circumspection and ethical care by researchers to avoid ‘unrealistic expectations and benefits’.

The subsequent sub-paragraphs (a) – (d) refer to research merit.

Paragraph 4.4.6. Is this factually correct? An emergency care research project should be set up before recruitment, whereas the recruitment aspect of the project entails repetition. The research project should involve careful explanation of the process for obtaining consent, including the use of independent advice if appropriate or available.

Paragraph 4.4.7. Is this paragraph not another example of processes to be followed and more appropriately included under Paragraphs 4.4.9-4.4.14?

Heading: Process to be Followed

These paragraphs are critical and important. They relate to the difficulties of obtaining appropriate consent, rather than process to be followed. Should the heading not be ‘Consent’ in these circumstances? As these paragraphs are so critical they deserve listing at the beginning of the section.

*Chapter 4.5: People with a Cognitive Impairment, an Intellectual Disability or a Mental Illness*

Paragraph 4.5.2. The second half of sentence 1: 'more susceptible than other participants to various forms of discomfort or distress' is vague. There are two considerations, not one: first, the relationship between impairment and voluntariness and consent; and secondly, susceptibility to discomfort and distress. Should both not be included and be required to be addressed in research proposals?

Paragraph 4.5.3. The use of the term 'justifiable' is rather tortious. The two sub-paragraphs refer to issues of research design, rather than entitlement to participate. Should the two ideas in sentence 1 and the rest of the paragraph be separated?

Heading: Beneficence

Paragraph 4.5.5. Is this paragraph not more concerned with respect for the individual and their best interest rather than 'beneficence'?

Paragraph 4.5.8. This paragraph could benefit from editing.

Paragraph 4.5.9. Is this paragraph not more concerned with HREC consideration of the project or research design.

Paragraph 4.5.10. Should the word 'should' not be replaced by 'must'?

*Chapter 4.6: People Who May Be Involved in Illegal Activities*

Paragraph 4.6.1. The word 'an' appears to be missing before the word 'identifiable' on the last line.

Paragraph 4.6.2. This paragraph is expressed awkwardly. It is proposed that the sentence be reworked to read 'research design to expose unlawful conduct may have an adverse impact on those whose conduct is exposed'. This is a consideration for an HREC that is not of itself, a reason for refusing approval.

Heading: Justice

The heading 'Justice' appears inappropriate for Paragraph 4.6.3. 'Legal Obligations' would be preferable. Research involving illegal activities has, itself, many legal consequences.

Paragraph 4.6.3. Delete the word 'foreseeably'.

Paragraph 4.6.4 should be moved under the heading 'Legal Obligations'. Why are different words used to those in Paragraph 4.6.2, namely 'design to expose unlawful conduct'?

Heading: Respect

Paragraph 4.6.5 does not appear to deal with respect but of possible professional conflicts of interest where a researcher involved with the person breached professional obligations. Surely something stronger than 'should ensure that the contact in a research role will not compromise contact in those other roles' should be included. At a minimum, there needs to be some cross-reference to the professional ethical responsibilities of the individual.

Paragraph 4.6.6. Delete the word 'foreseeably' in line 2. These sub-paragraphs are the positive ethical (and in some cases) legal obligations of the researcher. They should be placed at the front of the guidelines and certainly before paragraph 4.6.3.

Paragraph 4.6.7. This is very vague. It is not clear what has been stated. If it is a general point about care for a particular category of participant, perhaps this could be included in the text at the beginning of the sentence.

*Chapter 4.7: Aboriginal and Torres Strait Islander Peoples*

Why are the Principles listed as dot points, placed in a different order from the guidelines themselves?

Footnote 7 does not seem necessary and the additional words 'Commonwealth of Australia' at page 19 could be included in the text. Similarly, page references could be added at the end of each paragraph for the others.

Paragraph 4.7.1. The listing of considerations appear to falsely reflect the order of treatment so equipment, consent, feedback reporting could be a more logical flow.

Paragraph 4.7.2. Should the word 'sensitive' be replaced with the expression 'pay due regard'?

Paragraph 4.7.3. Should this paragraph not be listed first?

Paragraph 4.7.4 and 4.7.5 The heading 'Justice' does not appear appropriate as both paragraphs deal with questions of research design.

Paragraph 4.7.6-4.7.8 The heading 'Beneficence' does not appear appropriate as the paragraph deals with benefits to be derived.

Paragraph 4.7.6. 'Equally proportion'. Should the verbal noun be replaced with 'shared'. If, on the other hand, the idea is to have proportional shares, then the word 'equally' is inappropriate.

Paragraphs 4.7.9-4.7.11 deal with issues of design.

*Chapter 4.8: People in Other Countries*

This is an excellent chapter expanding on the spartan Principle 1.21 in the 1999 *Statement*. These guidelines set out a clear and comprehensive statement of responsibilities of Australian researchers towards people in other countries.

Paragraph 4.8.1. There are a number of the guidelines including 4.8.4; 4.8.6; 4.8.7; 4.8.12 and 4.8.18-4.8.19 that deal with the responsibilities of HRECs. These responsibilities are unique to this kind of research and deserve separate listing under the heading 'Role of HREC'.

Paragraph 4.8.2. Could this paragraph be expressed in two separate paragraphs, respect for local cultural values and respect to the standards of protection expressed in the *Statement*?

Paragraph 4.8.3. Should the paragraph not be expressed in two separate ideas, namely, HREC approved or equivalent approval in an overseas country and where this is not available, HREC in Australia consideration?

Paragraph 4.8.8. The words 'should be fair and the research should be neither opportunistic nor exploitative' should be rephrased. Is this not a question of research design and how will the HREC ensure this critical consideration?

Paragraph 4.8.10. Should this be reworded as 'where the HREC believes, on reasonable grounds, that a particular research project may perpetuate injustice, discrimination or economic or social disadvantage, the project should not be approved.

Paragraph 4.8.11. This is a most important principle referring to the overall responsibilities of institutions in good research governance. It ought to be listed under a separate heading 'Institutional, Legal and Moral Responsibility'.

Heading: Beneficence

Paragraph 4.8.13. The first sentence 'researchers need to know…communities' is not about beneficence, but about the qualifications of researchers to carry out the work. This should more appropriately be covered under the institutional sub-heading to the effect that institutions should ensure that researchers…have the relevant qualifications.

Equally, the next two sentences refer to safety factors and are the responsibility of the institution not the HREC.

Paragraph 4.8.14. This is a highly important section referring to complaint structures in a country. It should, at minimum, be reiterated in Chapter 5.6, that again, is an institutional responsibility rather than heading 'Beneficence'.

Paragraph 4.8.15. This is an issue of research design.

Paragraph 4.8.16. Again, this is the issue of risks and institutional responsibilities. It does not, however, have so much to do with the current heading. It should be repositioned in the chapter.

Heading: Respect

Paragraph 4.8.17. This does not deal with respect but rather research design as does paragraph 4.8.20.

**Section 5: Processes of Research Governance and Ethical Review**

This is a highly commendable section drawing together in a logical fashion the institutional, HREC and researcher responsibilities in ethical review (see comments above at Section 2: Themes in Ethical Review, where we propose transferring paragraphs from this section to a new combined Chapter 2.1).

*Chapter 5.1: Institutional Responsibilities*

As stated earlier this chapter and others in this section (including Chapters 5.3; 5.4; 5.5; 5.6 and 5.7) should be included as the opening chapter of the new *Statement*.

In addition, the paragraphs dealing with risk, (namely, paragraphs 5.1.3-5.1.6; 5.1.7-5.1; 5.1.15-5.1.20; and, 5.1.10-5.1.13) are very important and more logically placed with the Chapter dealing with risk, namely Chapter 2.1.

Heading: Research Governance

In this section a new paragraph 5.1.2 should be inserted, drawing together references to those points where institutions should develop policies for particular varieties of research. Most importantly, institutions should have in place policies and guidelines dealing with databanks, genetic research and human tissue. In addition, there should be a new paragraph, 5.1.3 referring to the various statutory responsibilities of institutions and researchers conducting research.

Paragraph 5.1.2 to be renumbered as 1.1.4 in Chapter 1.

Paragraph 5.1.4 [all references are to be current paragraphs subject to the overall recommendation to transfer some of these paragraphs to a new Chapter 1]. This paragraph should specifically refer to the categories of more than low, low risk and exempt.

The specific point of this guideline is the ability and authority of institutions to establish processes for ethical approval based on a level of review ‘proportional to any risk of the kind of research’. This deserves a separate guideline.

Paragraph 5.1.9. The last paragraph, last sentence is expressed awkwardly. It is proposed that the positive should be expressed, namely, ‘institutions must ensure that compliance with the requirements of the *National Statement*. Institutions should record any exemptions from ethical review involving low levels of risk.’

*Chapter 5.2: Responsibilities of Human Research Ethics Committees*

This is a very good chapter, well set out with clear sub-headings directing the HREC and researchers to the relevant sections and guidelines.

It is noted that there is a new sub-section with the heading 'Good Communication between HRECs and researchers'. This is commended. An ethical research culture within an institution and amongst researchers is not likely to be promoted by open and non-adversarial communication. It is proposed, that these three paragraphs could be included in a separate chapter recognising their importance.

*Chapter 5.3: Minimising Duplication of Ethical Review*

These guidelines are a commendable expansion and enhancement of the minimal treatment in Chapter 3 'Multi-Centre Research' in the 1999 *Statement*.

*Chapter 5.4: Conflicts of Interest*

Paragraph 5.4.1 and 5.4.3 all use the term 'managing conflicts'. It is proposed strongly that the expression 'managing conflicts' is not appropriate. The expression 'managing' appears to indicate that conflicts are inevitable, possibly acceptable and therefore something to be *managed* rather than avoided and addressed in ethically and legally appropriate procedures.

It is proposed that the term 'address' rather than 'manage' should be used.

Paragraph 5.4.1. The adjectives 'actual' or 'potential', conflate two quite separate circumstances with quite different consequences. It is better to separate actual from potential. An institution would have, expectedly, rather different processes for each.

Paragraph 5.4.2. Perhaps a sub-heading 'Researcher' should be placed above this paragraph.

Paragraph 5.4.3. The last sentence sets out different alternatives in addressing potential (rather than actual) conflicts of interest. These may be better listed as dot points. In addition, there should be two further dot points covering the options of:

- research should not be conducted; and
- research should be conducted by another independent researcher.

Paragraph 5.4.4. Should an interpretation of the expression 'review body' be included. In some cases this could be an HREC but it is more likely that it will not be.

Paragraph 5.4.5. This paragraph repeats the points in different ways from those expressed in 5.4.3. Should these two paragraphs not be made more consistent in lay-out and in text?

Paragraph 5.4.6. This is an important guideline proposing the use of independent advice. This, in law, is an important step where there are concerns about partiality, undue influence or conflicts of interest. This deserves a separate sub-heading.

*Chapter 5.5: Monitoring Approved Research*

This is a commendable section expanding and enhancing the 1999 *Statement*.

*Chapter 5.6: Handling Complaints*

This chapter includes a paragraph (5.6.1) in relation to scientific fraud or other scientific misconduct. This is an extremely serious, thankfully rare, circumstance. This should be better dealt with in a separate chapter with cross-references to the relevant provisions of the *Australian Code for the Responsible Conduct of Research*. In addition, some introductory comments should be included in relation to the importance to public trust in research and the requirement of personal integrity of researchers.

Furthermore, paragraph 5.6.5 deals with two separate circumstances, namely, researcher complaints about HRECs and participant complaints about the research project. Separate sub-headings would be helpful to direct readers to the appropriate guidelines.

*Chapter 5.7: Accountability*

As stated above, this is a very important chapter setting out a new and important direction in the governance of ethical research. It is proposed that this be moved to a new Chapter 2. The promotion of the discussion of research governance and accountability is consistent with the thrust of recommendations 14-1 and 17-1 of the Joint ALRC/AHEC Report, *Essentially Yours* which propose strengthening of the ethical review system.

Paragraph 5.7.1. Surprisingly, the standard headings in most chapters on 'research merit and integrity' did not include guidelines dealing with integrity. On the other hand, this paragraph does deal with the integrity of the researcher and their responsibilities for ethical design and conduct in research. The 1999 *National Statement* began in Principle 1.1 with the 'guiding value for researchers' being *Integrity*. Perhaps some of the wording from the old Principle 1.1 could be retained.

Should Paragraphs 5.7.1-5.7.3 have sub-headings of 'Researchers', 'HRECs' and 'Institutions' respectively?

## RESPONSES TO SPECIFIC QUESTIONS

i. Whether chapters 3.5-3.7 should be amalgamated?
**Response: No**

ii. Whether all human tissue is in principle re-identifiable?

**Response: Yes. We are happy to provide detailed justification if requested.**

iii. Do you agree with Paragraph 4.1.14 …?
**Response: Yes, these processes must be kept separate.**

iv. What are your views on the guidelines for children and young people?
**Response: It is essential that there are proper protections for children and young people consistent with the 1999 *Statement* and international standards. See our further comments above.**

## CONCLUSION

The Centre for Law and Genetics expresses best wishes to the working party in the drafting of the next version of the *Statement*. We reiterate our willingness to assist in any way requested in this important national endeavour. We have sought to present our submission in accordance with the instructions provided, in the form of re-editing suggestions without academic referencing or justification, which can be provided if required.

Professor Donald Chalmers
Dr. Dianne Nicol
Professor Margaret Otlowski
Professor Loane Skene
Dr. Mark Stranger