Review of Chapter 2.3 of the National Statement: Qualifying or waiving conditions for consent

1. General comments are welcome; however you may wish to consider the following:

We welcome the opportunity to comment on the revisions to the National Statement on Ethical Conduct in Human Research 2007. We are supportive of amendments to the National Statement to recognise an opt-out approach to participation in research projects. However we believe that it is important that any changes do not confuse an opt-out approach to participation with consent either legally or ethically. We believe that an opt-out approach to participation should be considered as a type of waiver of consent.

2. Please comment on the following definition of 'opt-out':

3. Please comment on the rationale provided for an opt-out approach (i.e. Section 3).

4. An opt-out approach to participation in research is a useful tool for enhancing trust by providing participants with information where explicit consent is not practicable. This approach will be particularly important in studies involving large numbers of participants where an explicit consent requirement may lead to statistical bias. An opt-out approach can be used to achieve a balance between respect for participants and the public interest in the conduct of valuable research.

5. Please comment on the proposed limited application of an opt-out approach (i.e. Section 4).

We would suggest that the structure of the amendments currently proposed should be reconsidered as it suggests that a lower threshold is required for an opt out approach as compared to a waiver of consent

If our assertion that an-opt out approach is actually an enhanced form of waiver then the same criteria should apply and it is unnecessary to have an additional section. Instead a further clause should be included under the waiver provisions requiring the HREC to consider whether the waiver should be subject to the implementation of an opt-out approach.

6. Please comment on the flow chart (i.e. Section 4).

The flow chart does not appear to take into consideration data collected in the course of routine care (e.g. clinical records) and mandatory statutory data collections. One would think these are examples of data where research use was anticipated but offering opt-out at the point of collection may not be feasible and may not be feasible or appropriate after collection. A fourth box (3d) should be added with an option for waiver of consent subject to HREC approval where privacy legislation applies.
Box 6b and 6d– the wording should be changed to "if privacy legislation applies". For some projects the Commonwealth Privacy Act will not apply but the State privacy legislation will require HREC review.

Box 3b – the wording should include 'HREC approval if privacy legislation applies'.

7. Please comment on the appropriate mechanism for providing information to participants for the opt-out approach represented at box 6d of the flow chart.

8. Please comment on the proposed amendments to the National Statement (see Attachment A underlined and in red text).

We suggest the following changes to the proposed amendments to the National Statement:

Chapter 2.3, Introduction Paragraph 6
Delete the word 'consent' in this passage and replace it with 'participation'. '*Depending upon the circumstances of an individual project it may be justifiable to employ an opt-out approach to* ***participation****. This is where a potential participant is provided with information approved by an ethical review body and, unless the participant communicates a choice not to participate in the research or related activity, their willingness to participate is presumed.*

Elsewhere the document refers to an opt-out approach and we think this is appropriate. Opt-out should not be confused with consent either legally or ethically.

Chapter 2.3, Introduction Paragraph 7
Suggest following additions to this passage - *A single research project may involve discrete elements or* ***participant groups*** *where different approaches to informed consent could justifiably be used. For example, a project may involve some elements or* ***participant groups*** *where explicit consent must be sought and other elements or* ***participant groups*** *where an opt-out approach may be considered or where a waiver of the consent requirement may be applied*

Chapter 2.3.9
An amendment to clause 5.1.6 is required to add 'research where HREC review is required by privacy legislation' to the types of research that require review by an HREC.

Chapter 2.3.10 g), h) and i)
We believe that these are requirements for all research projects and are not specific to research using an opt-out approach. They would be more appropriately included in general provisions on the use of data in a revised chapter 2.3.

9. Are there situations where an opt-out approach might be appropriate that have not been considered in the proposed amendments?

10. Are there any situations you can think of where the draft amendments would allow an opt-out approach that may be inappropriate?

11. Can you provide examples where an opt-out approach may be useful?

12. General comments.

We would like to encourage the NHRMC to take this opportunity to review the whole of Chapter 2.3 in addition to the specific consultation on an opt-out approach. There are a number of issues that should be considered including:

- An amendment to Chapter 5.1.6 is required to add research where HREC review is required by privacy legislation to the types of research that require review by an HREC. In our experience many HRECs find the fact that this is not listed as one of the types of research which require review by an HREC to be confusing.

- The relationship between 2.3.6(a) and 5.1.6 - 5.1.7

- 2.3.6(c) - reconsider the word "impracticable" and include consideration of
    - the impact on people of seeking consent and
    - whether the outcomes of the research will be compromised

- The difficulty of applying 2.3.6(d)

- Should legality be a question for the HREC - 2.3.6(i)? This is more appropriately a question for research governance or data governance. It appears to require that HRECs obtain legal advice on each occasion.

- Clarify the responsibility in 2.3.8. Is this the responsibility of the institution conducting the research or the institution providing ethical review? Either way there does not appear to be compliance so it does need reconsideration. Why is it here and not in chapter on institutional responsibilities?