National Statement on Ethical Conduct in Human Research Section 4
Response to the Consultation, September 2023

Background

The National Statement on Ethical Conduct in Human Research, provides guidelines for researchers, Human Research Ethics Committees (HRECs) and others conducting ethics review of research, but also emphasises institutions’ responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.

The NHMRC undertakes a rolling review of the National Statement on Ethical Conduct in Human Research, examining one section at a time. The revised draft section 4 provides advice for both researchers and Human Research Ethics Committees (HRECs) addressing ethical considerations specific to participants in research.

Section 4 underwent a previous public consultation in 2020 and the draft revised sections were accompanied by explanatory material to provide clarity about the changes in structure and content that have been introduced to these sections. The statement places a particular emphasis on an inclusive approach to research participation and consideration of the potential research participants, their characteristics and circumstances as individuals.

NHMRC sought feedback from interested parties, in particular on whether the revised section:

- provides sufficient guidance to address the key ethical considerations specific to participants in research
- is presented and written in a manner that is appropriate for the target audience (researchers, HRECs).

Responses to the draft Section 4 were sought by response to specific questions in an electronic survey.

This document provides Research Australia’s responses to the survey questions.
Response to the survey

Question 1: Is the scope of Section 4 appropriate and is it adequately defined?

The scope is appropriate.

Question 2: Do the enumerated chapters fully capture the issues that are within the scope of Section 4?

Yes.

Question 3: Language related to sex and gender is evolving, particularly in the context of references to pregnancy. Do you have any input on whether the language used in the revised Chapter 4.2 is appropriate and, if not, with what it should be replaced?

The language is clear and appears to be inclusive.

Question 4: If you have any other input related to Section 4 that you would like to provide, please do so here.

Research Australia supports the emphasis in Section 4 on including as many people as possible in research and on considering their individual characteristics and circumstances in assessing the risks and benefits to the individual of participating, individualised approaches to mitigating risks, and to obtaining consent. We note that such an individualised approach comes at a greater cost in terms of the time and effort required to recruit and support some research participants who would likely have been excluded in the past. It also potentially requires additional capability and expertise within the research team (including specific training of research team members) and/or the use of expert assistance from outside the team. Research Australia believes it is important that this additional time and cost is reflected in research budgets and timeframes and recognised by research funding programs.

The Introduction to Section 4 (page 1) includes asylum seekers and people involved in illegal activity in the one dot point in the discussion of circumstances that increase risk. Research Australia suggests that doing so is insensitive and implies asylum seekers are engaged in illegal activity. Research Australia suggests a new separate dot point is added for persons engaged in illegal activity.

In Chapter 4.1 (page 3) poses this question: ‘Is there an increased risk of harm to potential participants in this project?’ The purpose is to consider the increased risk of harm to an individual because of one or more of their characteristics or circumstances. Research Australia
suggests the question should be ‘Is there an increased risk of harm to some individuals in the pool of potential participants in this project?’

The following question should be ‘How can we design, or modify the design of, and conduct our research so as to minimise, mitigate and manage the increased risk to some individual potential participants (with consideration for recruitment, consent, ongoing participation and the potential outcomes of the research)?’

In Chapter 4.2 (page 1) there is a typographic error (‘has’ should be ‘have’): ‘Attempts to avoid this risk has traditionally led to…’

In Chapter 4.4 (page 1) there is a reference to ‘carers and people…’ in the first dot point. It seems the reference to carers is to ‘paid care workers’ but the language is ambiguous. Failing to distinguish family and friend carers from paid care workers is an issue in many documents addressing the carers of people living with disability. Research Australia suggests using the expression ‘paid care workers’ and other terminology in a manner consistent with the Carer Recognition Act 2010 (Cth).

In Chapter 4.5 para 4.5.25 there is a typographical error (the word ‘to’ should be deleted): ‘

As with any person experiencing ill-health, people who are dying may be more likely to experience to certain harms;…’

**Question 5:** Does the new or modified language in the Preamble and Section 1 achieve the intended objective of supporting the revised Chapter 4.7: Research with Aboriginal and Torres Strait Islander peoples and communities?

Research Australia assumes the authors have already checked the language with the appropriate representative bodies, and should do so if this is not the case.

**Question 6:** If you have any input related to the Purpose, Scope and Limits section that you would like to provide, please do so here

No input to provide.

**Question 7:** If you have any input related to the change to paragraph 1.2 that you would like to provide, please do so here.

Research Australia supports the new wording of paragraph 1.2

End of survey response
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Our vision: Health and prosperity through Australian research and innovation.

Our mission: Use our unique convening power to maximise the impact of all stages of health and medical research and innovation.

Our role:

Engage
Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect
Researchers, funders, healthcare providers and consumers to increase investment in health and medical research from all sources.

Influence
government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes

Established with the assistance of the Federal Government in 2002, Research Australia is the national alliance representing the entire health and medical research (HMR) pipeline, from the laboratory to the patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

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