



Consumers Health  
Forum OF Australia

SUBMISSION

# Consultation on the National Statement on Ethical Conduct in Human Research

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Consumers Health Forum of Australia (2023)  
*Consultation on proposed revisions to Section 4 of  
the National Statement on Ethical Conduct in  
Human Research*  
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## Introduction

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Consumers Health Forum (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in healthcare consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems. At the heart of CHF's policy agenda is consumer-centred care.

CHF appreciates the opportunity to provide a submission to the National Health and Medical Research Council regarding the National Statement on Ethical Conduct in Human Research (the Statement).

## Consultation

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Consumers from CHF's Research and Data Special Interest Group were consulted on the proposed changes to the Statement. This group brings together consumers with interest and experience in health research and policy. A facilitated discussion was held in August to gauge consumer views and perspectives which provided a range of insights relating to participant recruitment, assent and consent. Additionally, consumers provided their thoughts on the language and readability of the document with a view towards engaging with and reaching a wider audience.

## Definition of research

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The proposed version of the Statement includes a change to the definition of research in the Purpose Scope and Limits section. CHF supports the inclusion of the Australian Research Council's definition of research. On this discussion point, consumers highlighted the need for definitions to remain interoperable across international settings and the need for ethical research to conform with both Australian and international ethics research standards. CHF supports the Statement's intent to be consistent with international human rights instruments.

Consumers discussed their experiences with past research studies and stated the importance of control and access during research, highlighting the importance of having access and ownership of their own biological samples and data when it is central to their care. CHF supports the inclusion of these ethical considerations in the updated Purpose Scopes and Limits section of the Statement and notes that the 2018 revision to Chapter 3.2 '*Human Biospecimens in Laboratory Based Research*' more fully captures these ethical considerations for research participants. Additionally, CHF supports the specific guidelines in Chapter 4.2 '*Pregnancy and the human fetus and human fetal tissue*' where guidance highlights the specific considerations for research with biological tissue from human fetuses in utero or after separation from the pregnant woman.

## Review of the application of ethics guidelines

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Following consultation on the changes made to the “When is an ethical review needed?” section, consumers highlighted the merits of considering the ethics of the research at multiple stages of the research process. As well as considering the ethical implications of research prior to the study taking place, consumers recommended that a second review of the guidelines could occur at the conclusion of the research project. This second review would indicate to researchers and research institutions whether ethics guidelines were adequate and if they were correctly applied to the project. This could then produce improvements for both specific future projects and ethics processes more broadly.

Without a review process, there is no mechanism by which to assess whether the guidelines are functioning as intended and are providing safe and culturally appropriate participation for research participants.

## Additional guidance for participants who may experience increased risk

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CHF supports the addition of Chapter 4.1 *“Ethical issues in recruitment and involvement of research participants who may experience increased risk”* to the Statement. The chapter highlights the sources of increased risk for participants in research and discusses surrounding consent in research participation. Consumers discussed the fact that characteristics relating to physical or mental ill-health or disability were important factors for inclusion in the Statement and CHF supports the newly combined Chapter 4.5 *“People experiencing physical or mental ill-health or disability”*.

Consumers noted that many of the ethical considerations regarding Aboriginal and Torres Straight Islanders communities and individuals also pertain to many individuals from culturally and linguistically diverse (CALD) communities who are living in Australia. It is important for the Statement to consider the cultural considerations for individuals from CALD backgrounds. While Chapter 4.1 notes that cultural factors may be associated with increased risk in participation of research, the addition of ethics guidance for research with individuals from CALD backgrounds would be welcomed.

## Assent and consent

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CHF supports the addition of consent and assent guidelines in Chapter 4.3 *“Children and Young People”*. CHF suggests that the inclusion of the topic of assent could be included more broadly across the Statement. For example, assent considerations could be applied to the guidelines amongst other groups and could be mentioned in Chapters 4.1 and 4.5, respectively.

Through discussions around consent and assent, consumers were eager for the Statement to include considerations of dynamic consent. As the dynamic consent approach encourages research participants to make ongoing decisions about their research participation, this would

foster greater communication between researcher and participant while supporting individuals to review their consent throughout the research process.

Consumers highlighted the different considerations that may need to be applied in research with participants from individual or collective cultures. CHF supports the inclusion of considerations for collective cultures mentioned in the guidelines under section 1.10. There are vital considerations when considering research with individuals from collectivist cultures (for example pertaining to consent in participation) and it would be beneficial for these considerations to be incorporated into the guidelines within other relevant sections of the Statement, such as in Chapter 4.6 *“Research conducted in other countries”* and in Chapter 4.7 *“Research with Aboriginal and Torres Strait Islander people and communities”*.

## Considerations in participant recruitment

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Consumers emphasised some of the issues surrounding recruitment of participants particularly in older Australians and with individuals from culturally and linguistically diverse backgrounds. CHF supports consulting with local communities and encourages the co-design of research projects with the potential participants or communities with whom the research is to be conducted.

CHF supports the risk mitigation strategy put forward in the Statement as it highlights the need for additional strategies to mitigate, minimise and manage risk amongst participants who may be at increased risk of harm. CHF supports this strategy because it is known that the historical approach for research ethics processes was to often exclude such potential participants, leading to knowledge gaps about certain groups, when they would greatly benefit greatly from the outcomes of focused research.

## Fostering public engagement

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While the language of the document is fit-for-purpose for academic researchers and Human Research Ethics Committees (HRECs) and thus is aligned with the Statement’s intended purpose, the Statement is not particularly accessible to a wider audience. This is of particular importance as members of the public who become or consider becoming research participants need resources and support in assessing whether the research they are considering is being conducted in an appropriate and ethical manner.

This sentiment has been reflected by consumers who feel that there is an opportunity for greater engagement on ethics issues in the wider population. CHF and consumers propose that the NHMRC consider designing a companion document for the Statement that explains research considerations for participants in easy-to-understand language that is presented in accessible formats.

In order to better foster public engagement with research, consumers indicated a desire for such a companion document to be publicised to a wider audience to increase general knowledge of ethics guidelines in the general population. Such a document could help to facilitate participant and consumer involvement in the research process.

## Specific wording suggestions

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To better capture the need for research to be co-designed with consumers, the following specific word changes are proposed.

### Section 1

- 1.1a. Remove “*may*” in second sentence. Relevant communities should be involved in assessing potential benefits of research in their communities.
- 1.1b. Change to “*co-designed with consumers...*”
- 1.1d. Change to “*co-designed with consumers...*”
- 1.4a. Add that research participants are representative of the diversity of the population.
- 1.5. Add “*Research progress and outcomes should be made accessible to research participants and the wider community in a way that is timely and clear.*”
- Application of these values and principles section. This section notes that there are other ethics guidelines and documents that are available for research in specialised areas of research. Here it may be useful for researchers to have these additional guidelines and documents linked in this section. For example, a link to the NHMRC-CHF joint Statement on consumer and community involvement in health and medical research as this document aims to guide researchers in the active involvement of consumers and community members in health and medical research.

### Section 4

- 4.2.14. This guideline should also mention the health of pregnant women.

## Conclusion

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CHF broadly supports the revision to the Statement and values the Statement’s focus on discussing exposure to risk rather than perceived vulnerability for certain groups. This is a positive move away from labelling individuals or groups as vulnerable based on physical, cognitive, social, economic or cultural factors, towards the notion that vulnerability is not a fixed state. This is a beneficial approach as it considers each individual within the specific circumstances of the research project with which they are engaged.

The document does not sufficiently mention the benefit to consumers in engaging with the research process, or the benefits to research itself in having consumers engaged with the process. The benefit to consumers should be at the forefront of the research question, not a consideration after the design of the study protocol. Documents such as the Consumer Toolkit and National Framework for Consumer Involvement in Cancer Control produced by Cancer Australia highlight the benefit in involving consumers in the design stage of a research project. The document discusses many of the issues raised through the discussions held with consumers in regards to this Statement, namely that greater involvement with consumers ensures that issues which are important to consumers are identified and prioritised. Additionally, the Consumer Toolkit highlights how involving consumers in research can support the dissemination of results from research.

In order to better capture the need for greater collaboration between researchers, consumers and communities, CHF emphasises the need for the Statement guidelines to support co-design with consumers at all stages of the research process. Additionally, CHF highlights the importance of encouraging greater interest from a wider audience outside of researchers and HRECs on matters of ethical research.