

## UNIVERSITY OF CANBERRA HUMAN RESEARCH ETHICS COMMITTEE (HREC)

### LESSONS LEARNT FOR 2021

During 2021 there were a number of issues that the Human Research Ethics Committee (HREC) identified across a number of applications. It is hoped that this document will help others to learn from these applications with a view to improving researchers' experience of seeking ethics approval.

These five points were identified as not being sufficiently addressed in at least one application in every 2021 HREC meeting. These are not the only issues, but they are issues that are easily addressed through researchers having a little more understanding of how applications are considered. The application process should be seen as a conversation between the researcher and the HREC with a view to promote the conduct of ethical research.

[The National Statement on Ethical Conduct in Human Research](#) (the National Statement) is founded on four principles. These are research merit and integrity, justice, beneficence, and respect. It is these principles that form the basis of the guidance provided within the National Statement. The discussion below links these issues with the relevant passages in the National Statement on Ethical Conduct in Human Research (the National Statement) to provide researchers with a better understanding of the deliberations of the HREC.

#### Justify the proposed research proposal

The intent of Section 8.1 on the application form is to satisfy the HREC that this proposal meets the requirements under the National Statement that research demonstrates **research merit**. Paragraph 1.1 of the National Statement provides guidance to reviewers, and to researchers, on the components of research with merit.

Section 8.1 asks applicants to: **Please provide a justification for your research based on a literature review (including references for citations)**. It is common, particularly for students and early career researchers to provide evidence of a gap in the knowledge or identify an area of research that needs to be addressed. This is only part of the response required here. The HREC needs to see applicants take the next step and explain how this specific research proposal will address that gap in knowledge or answer this important question.

### **Explain why the selected cohort is appropriate for the research project**

Paragraphs 1.4 and 1.5 of the National Statement establish the how justice is viewed within the guidelines. In particular, 1.4 (a) calls on researchers to *take into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair and is accurately described in the results of the research.*

Questions 11.1, 11.2, and 11.4 try to establish if the intended participants are the right group of people to answer the specific research question. Research should seek to enrol participants who are relevant to the research question, and only those people. Where the sample cohort does not support generalisation, that should be properly articulated when describing the research findings.

An example of this issue is where a researcher may conduct a research into Australian attitudes to hats, survey only university students, and then assert that the findings are relevant to all cohorts across Australian society.

### **Provide an explanation of the sample size selected**

Paragraph 1.1 (b) and 1.4 of the National Statement are relevant to addressing this issue. Ensuring a valid sample size is a matter of both, methodological merit and justice. It is a matter of research merit that sufficient sample size be recruited to ensure meaningful and substantiated conclusions. It is a matter of justice that researchers should ensure that no more people are inconvenienced by research than are needed to reach these conclusions.

Question 11.5 asks that applicants detail how many participants will be recruited and the rationale for that number. This ought to include a discussion of the methodological basis for the research approach. The discussion should explicitly link the chosen method to the research question and explain why this is a relevant cohort to answer this specific question.

It is not sufficient to indicate that numerical data will be analysed using SPSS, or that the number selected is based on a similar study – unless the research is intending to replicate that study.

## Participant information and consent forms

Participant information must be accessible to the intended research cohort. Researchers should communicate using plain English wherever possible. The use of jargon and acronyms should be kept to a minimum. It is generally inappropriate to cut and paste sections of grant applications, or ethics applications, into the information provided to participants. [The Australian Government Style Manual](#) provides clear guidance to help draft participant information in a way that enhances the accessibility of information.

Researchers should be familiar with Chapter 2.2: General Requirements for Consent before they begin to draft their participant information. The Research Office provides templates to assist but the content must be specific to the research proposal. A number of issues arise on a regular basis, these include:

- wording must be appropriate for the comprehension level of the participants (para 2.2.3 – 2.2.4)
- participants must be informed of both the risks and benefits of their participation (para 2.2.6)
- an explanation should be given as to what will be done with data (Section 3, Element 4: Collection, Use and Management of Data and Information) or biological material collected during the research; including tissue, blood, urine, and sputum (para 3.2.12), once the research is completed.
- participants need to be given sufficient information to make a decision when asked if data or tissue can be kept for use in future research (paras 2.2.14 – 2.2.18).

Committee members will need to be assured that participants are properly informed about the steps that will be taken to ensure that data is kept confidential and that, where appropriate, data will be anonymised. These assurances should be stated in plain English in the information provided to participants.

## Consistency

It cannot be stressed enough that applications for ethical approval for research need to be consistent. While it is not an ethical requirement that the application be free of spelling and grammatical errors, inconsistencies where the application contradicts itself raise doubts in the minds of reviewers. The application should be written in clear, concise, everyday language. The use of acronyms should be explained, and discipline specific terms clarified. While your

application will be reviewed by HREC members with expertise in your field, it will also be reviewed by HREC members who are not experts in your discipline.

When applications are clear, concise, and consistent, they are easier to understand, easier to review, and the focus of the HREC can be more on understanding the ethical implications of the research. A clear application promotes meaningful dialogue between the HREC and research community.

### **Multi-Phase Studies**

It is common for research studies to be divided into phases, or to be based on previous research. Where this is the case, researchers can assist the committee in their consideration of their application through providing evidence of the outcomes and learnings from previous research.

Where a research project is conducted in phases, please provide a summary of the outcomes of the previous research, highlighting how lessons learned through the conduct of the previous research will inform future research.

Where a research project is based on data previously collected for research purposes, it is helpful to provide a copy of the participant information and consent documentation to demonstrate that participants have consented to the information being used in a manner consistent with the current proposal.

Useful Links:

[Human Research Ethics Manual](#)

[Privacy Act 1988 \(Commonwealth\) Section 14, Schedule 1 - Australian Privacy Principles](#)

[UC Human Ethics homepage](#)