# University of Canberra Human Research Ethics Committee

## Lessons Learnt 2022

Applications to the Human Research Ethics Committees (HREC) during 2022 were of variable quality. Some of the applications, including student research applications, were of very high quality. However, there were recuring issues that were evident in at least one application on the agenda of every meeting of 2022:

- An inadequate literature review
- Insufficient justification of the proposed research – not merely research on the topic; and
- Informing participants about the nature of the research

## The National Statement

The National Statement on Ethical Conduct in Human Research is the primary guidance document used by HREC when assessing the ethical acceptability of a research proposal. SECTION 1: Values and principles of ethical conduct of the National Statement[1] provides the framework for the whole of the document. Every person involved in the development, conduct, or evaluation of human research ought to be familiar with the four key principles of the National Statement. Human research projects must adhere to the core ethical principles described in Section 1 of the National Statement. These principles apply at all stages of a research project from inception to post-completion.

<u>Research merit and integrity</u> (National Statement paragraphs 1.1 – 1.3)

Human research always involves people, whether as individuals, groups, or communities, through direct interaction, observation, using their data or information about them, or tissue samples. HRECs must be satisfied that the research is worth undertaking. Applications must demonstrate that they add to the body of knowledge, improve social welfare or individual wellbeing, or advance research practices in order to justify the involvement of people as research participants.[2]

## Literature Review

The literature review is a key piece of the application used by the Committee to assess research against the National Statement requirement that research that is ethical is conducted for a purpose and uses methods that have integrity. It is in the best interests of the applicant to:

1. Establish a gap in the literature with respect to understanding, practice, or policy
2. Propose a research approach to fill, or address, that gap
3. Show how the proposed approach is credible

---

[1] National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra, (pp9 – 11)

[2] Pieper I, Thomson CJ. Contextualising merit and integrity within human research. Monash Bioeth Rev. 2011 Sep;29(4):15.1-10. doi: 10.1007/BF03351329. PMID: 22397090.

4. Provide an indication of how the results will be used, or disseminated so that they fill the identified gap.

Justice (National Statement paragraphs 1.4 – 1.5)

Researchers have an obligation to ensure that the research that they conduct is just. HRECs have a responsibility to identify justice issues within an application and to objectively describe any issues in the context of the principles in the National Statement.

## Clarify the Risks and Benefits

The assessment of a research application needs to consider:

- who will benefit from the study;
- what will those benefits be and how will they be accessed; and
- on whom the burden of risk will fall

Any application for ethics approval needs to demonstrate that the study cohort has been chosen for methodologically valid reasons and that the burdens that the study will place on them can be justified.[3] Often research participants bear the burdens of research and receive little, or no, benefit. Applicants should be clear about how the risks and burdens of the research are justified by the benefits.

## Consider the research cohort and the implications of the research more widely

1. Research involving teachers where students will be tested or engaged has as participants students – not just teachers
2. Research aimed at changing professional practice will impact on the recipients of that practice. Identify the risks and benefits of this flow-on effect

Beneficence (National Statement paragraphs 1.6 – 1.9)

The likely benefit of the research must justify any risks of harm or discomfort to participants.[4] This is a difficult, subjective, and nuanced consideration. To do no harm, is not the same as actively providing benefit. The term beneficence refers to actions which help others. A beneficent act is one which promotes the betterment of others for altruistic reasons. Beauchamp and Childress refer to beneficence as a positive contribution list three components that ought to be present in research which demonstrates beneficence:

- to prevent evil or harm;
- to remove evil or harm; and
- to do or promote good.

Paragraph 1.7 of the National Statement places the responsibility on researchers to:

- design research to minimise the risks of harm or discomfort to participants;
- clarify the potential benefits and risks of the research of participation; and

---

[3] Pieper, I., Thomson, C.J.H. Justice in Human Research Ethics. Monash Bioethics Review 31, 99–116 (2013). https://doi.org/10.1007/BF03351345

[4] National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), (paragraph 1.6).

- promote the welfare of the participants within the research context.

These considerations should be inculcated throughout each of the research elements listed in Chapter 3.1 of the National Statement.

<u>Respect</u> (National Statement paragraphs 1.10 – 1.13)

In order to continue to maintain public trust and confidence in human research, participants must be treated with respect. One of the key components of respect in human research is a valid consenting process. Researchers and HREC members need to be aware that modern considerations of this value include, as principles:

- the protection of participants who have their capacity for consent compromised;
- the promotion of dignity for participants; as well as
- consideration of the implications of human research on cultures and communities.

Dignity is used extensively in international guidelines to refer, not just to respect for autonomy but also, respect for individual relationships and avoiding humiliation. Respecting dignity includes providing a process to facilitate and support a person's ability to choose how to live in accordance with their own desires and values and to promote their own best-interest. The most obvious manifestation of respect in human research is demonstrated by supporting the potential participant's meaningful choices. To make meaningful choices, participants must be provided with meaningful information.

## Participant information

Consent should be a voluntary choice, and should be based on sufficient information and adequate

understanding of both the proposed research and the implications of participation in it. The Committee takes the view that being provided with information is not the same as developing an adequate understanding. Participant information should be delivered in a way that supports decisions that reflect their preferred choices.

Participant information must consider:

- Content and message;
- The medium used to convey the information;
- Language and phrasing;
- Pictures, infographics, or diagrams may help to inform participants; as well as,
- Context and cohort circumstances, participants should have the time and attentiveness to properly consider decisions about participation.

Chapter 2 of the National Statement provides guidance on the general requirements for consent. All applicants and researchers are strongly urged to familiarise themselves with paragraph 2.2.6 as a minimum when preparing the participant information for a study.

## Further Reading

Beauchamp T. L. & Childress J. F. (2019). *Principles of biomedical ethics* (8th). Oxford University Press.

Have, H. ten. & Jean, Michèle. & Unesco. (2009). *The UNESCO Universal Declaration on Bioethics and Human Rights : background, principles and application*. Paris : UNESCO Publishing https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights

International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016 https://doi.org/10.56759/rgxl7405

Killmister, Suzy, 2014, *Dignity: not such a useless concept*, J Med Ethics 2010;36:160e164. doi:10.1136/jme.2009.031393

Jonas, H *Philosophical Reflections on Experimenting with Human Subjects*, Daedalus, 1969, Vol.98, No. 2, pp.29-246

Macklin R. *Bioethics, vulnerability and protection*, Bioethics 17 (5–6), 2003, 472–485.

Mastroianni, Anna C., & Kahn, Jeffery P., *Swinging on the pendulum: Shifting views of justice in human subjects research*, Hastings Center Report 31 (3), 2001, 21–28.

National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Pieper, Ian J. (2022) Relational autonomy in clinical research: Relational considerations of adult participation in clinical research. PhD thesis, Queensland University of Technology. https://eprints.qut.edu.au/231386/

Spriggs, Merle, 2010, *Understanding Consent in Research Involving Children: The ethical issues A Handbook for Human Research Ethics Committees and Researchers.* Children's Bioethics Centre, Murdoch Childrens Research Institute, version 4, 2010.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 'The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research,' Maryland: Department of Health, Education and Welfare, 1979 https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html