University of Canberra Human Research Ethics Committee

Lessons learned 2023

Human Participants in Research

"Human research is research conducted with or about people, or their data or tissue."[1]

Identification of participants in research projects and the justification of inclusion and exclusion criteria continues to be problematic. Researchers must remind themselves that participation in research is voluntary and that it is their responsibility to justify the inclusion – and the exclusion – of identified cohorts. Section 3, Elements 1 to 3 of the National Statement (Research Scope, Aims, Themes, Questions and Methods; Recruitment; and Consent) should be considered in detail when researchers are determining the required cohort for research protocols.

If a research project includes, or is about people, their data, or their tissue then it is human research. Accordingly, if a person, their data, or tissue is involved in the conduct of your research, then they are participants and must be afforded the respect and courtesy due to participants in research. This includes research that observes how people interact with each other such as in a classroom, lecture theatre, clinical space, or in a public area. Each person involved in the observation is a participant in the research.

Participation in human research is voluntary. Participants must be given the opportunity to consent or opt-out of the study, or a waiver must be sought for their inclusion. In the case of health and medical research, that waiver may only be granted by a Human Research Ethics Committee. If a waiver of consent is sought, the applicant MUST address sections 2.3.9-2.3.12 of the National Statement whether, or not, the waiver application goes to the full HREC.

Justifying Inclusion of Participants

Researchers should consider the impact that including certain cohorts may have on the the capacity of a research proposal to demonstrate the principles of the National Statement. Participant selection has implications under each of the principles.

The National Statement principles guidance that is most particularly relevant to considering inclusion criteria for human research participation are:

Research Merit and Integrity[2]

The inclusion of participants in research must be justifiable in terms of their contribution to answering the research question. People should only be included in research where it is ethically and methodologically justifiable. When designing protocols, researchers should include all of the participants necessary to answer the research question fully.

---

[1] National Health and Medical Research Council, Australian Research Council and Universities Australia (2023). National Statement on Ethical Conduct in Human Research 2023. Canberra, National Health and Medical Research Council.
[2] Pieper, I. and C. J. H. Thomson (2011). "Contextualising merit and integrity within human research." Monash Bioethics Review **29**(4): 15.11.

National Statement Paragraph 1.1 describes research that has merit as including:

> (b) designed or developed using methods appropriate for achieving the aims of the proposal
>
> (d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;

Justice[3]

The Belmont Report introduced justice as a basic principle that ought to be present in the ethical conduct of human research: "Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of 'fairness in distribution' or 'what is deserved.' An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."[4] The Belmont Report explicitly links justice to recruitment through the following: "the selection of research subjects should avoid the selection of populations merely because they are available, are in compromised positions or are manipulable, rather than 'for reasons directly related to the problem being studied."

The National Statement provides guidance through paragraph 1.4, research that is just:

> (a) takes 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;
>
> (b) the process of recruiting participants is fair;
>
> (c) there is no unfair burden of participation in research on particular groups;
>
> (d) there is fair distribution of the benefits of participation in research;
>
> (e) there is no exploitation of participants in the conduct of research; and
>
> (f) there is fair access to the benefits of research.

Beneficence[5]

Beneficence is a moral ideal, an aspirational principle which promotes good or charitable outcomes, over and above those imposed by duty. Beneficence is essential as a principle that is demonstrable within ethical research because research is a voluntary exercise which rarely benefits participants directly or necessarily as a result of involvement in the research.

Paragraphs 1.6 and 1.7 of the National Statement provides guidance on the implications of beneficence as a principle when considering recruitment for ethical human research:

---

[3] Pieper, I. and C. J. H. Thomson (2013). "Justice in human research ethics. A conceptual and practical guide." Monash Bioethics Review **31**(1): 99.

[4] 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, 8.

[5] Pieper, I. and C. J. H. Thomson (2016). "Beneficence as a principle in human research." Monash Bioethics Review **34**(2): 117-135.

Paragraph 1.6 - The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

Paragraph 1.7 - Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

Respect[6]

Respect is a central concept within human research ethics. Respect for persons involves promoting and enabling each individual's freedom to make meaningful choices about participation. For research to be ethical, it is not enough to merely permit choices: respect for participant autonomy must be actively promoted and their dignity guarded. People should only be recruited if there is a meaningful purpose to their inclusion in the research. Respect in research also includes demonstrating respect for communities, cultures and social groups. Interacting respectfully with people from different cultures requires recognition of their history in the ways that we communicate and inter-relate.

Paragraphs 1.10-1.12 provide guidance on how the principle of respect is relevant to the recruitment of people for research.

Paragraph 1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

Paragraph 1.11 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled.

Paragraph 1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

---

[6] Pieper, I. and C. J. H. Thomson (2015). "The value of respect in human research ethics: a conceptual analysis and a practical guide." Monash Bioethics Review: 1-22.

Justifying Exclusion of Participants

Researchers should also consider the impact that exclusion of certain cohorts may have on the the capacity of a research proposal to demonstrate the principles of the National Statement. Participant selection has implications under each of the principles.

The National Statement principles guidance that is most particularly relevant to considering exclusion criteria for human research participation are:

Research Merit and Integrity

The exclusion of participants in research must be justifiable in terms of their contribution to answering the research question. Excluding cohorts may invalidate research findings. People should only be excluded in research where it is ethically, legally, or methodologically necessary. Researchers should not exclude participants on the grounds of convenience, availability, or increased complexity.

National Statement Paragraph 1.1 describes research that has merit as including:

> (b) designed or developed using methods appropriate for achieving the aims of the proposal
>
> (d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results

Justice

When excluding identified cohorts from participation in research, researchers should consider the ethical implications inherent in the decision:

- Is it fair to exclude these groups?
- Will the exclusion of these groups impact on the generalisability of the research outcomes?
- Will particular cohorts or individuals be disadvantaged if the benefits of the research cannot be extended to them through their exclusion from the dataset?
- Will particular groups feel disrespected or that their exclusion is unfair?

The National Statement paragraph 1.4 states that research is demonstrably just when:

> (a) it takes 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;
>
> (b) the process of recruiting participants is fair;
>
> (c) there is no unfair burden of participation in research on particular groups;
>
> (d) there is fair distribution of the benefits of participation in research;
>
> (e) there is no exploitation of participants in the conduct of research; and
>
> (f) there is fair access to the benefits of research.

Beneficence

Beneficence relates to justifying the risks involved in the conduct of research through the benefits that are expected to emerge. Benefit and risk within a research project can be difficult to identify and are amongst the most subjective aspects or ethics review. Both risks and benefits associated with a research project often extend beyond those associated with the participants directly.

Beneficence may be compromised when specific cohorts are excluded from research that may prove beneficial to a cohort with which they identify. For example, excluding people under 18 from a study looking at the experiences of first year university students.

When considering the principle of beneficence in research, the National Statement provides the following guidance:

Paragraph 1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

Paragraph 1.7 Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

Respect

People should not be excluded from participation in research merely because they are difficult to engage, have diminished or compromised capacity, or are vulnerable. It is the responsibility of the researcher to ensure that appropriate precautions are in place to engage with the necessary research cohort with respect.

When considering the principle of respect in research, the National Statement provides the following guidance:

Paragraph 1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence.

Paragraph 1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

Summary

The inclusion or exclusion of specific groups and cohorts from research has the capacity to dramatically impact on the ethical acceptability of a research proposal. Researchers have an obligation to consider recruitment practices more widely than convenience, availability, or being a captive audience.

Further Reading

National Health and Medical Research Council, Australian Research Council and Universities Australia (2023). National Statement on Ethical Conduct in Human Research 2023. Canberra, National Health and Medical Research Council.

Pieper, I. and C. J. H. Thomson (2011). "Contextualising merit and integrity within human research." Monash Bioethics Review **29**(4): 15.11.

Pieper, I. and C. J. H. Thomson (2013). "Justice in human research ethics. A conceptual and practical guide." Monash Bioethics Review **31**(1): 99.

Pieper, I. and C. J. H. Thomson (2015). "The value of respect in human research ethics: a conceptual analysis and a practical guide." Monash Bioethics Review: 1-22.

Pieper, I. and C. J. H. Thomson (2016). "Beneficence as a principle in human research." Monash Bioethics Review **34**(2): 117-135.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, Maryland: Department of Health, Education and Welfare.