



Checklist: Research protocol

May 2024

Australia's Human Research Ethics Committees (HRECs) are required to assess research applications according to National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research* (2023). These are also to be used by other bodies reviewing research.

The tables below summarise key ethical research requirements identified in the National Statement that achieve the values of the National Statement. They serve as a basic checklist to ensure that items are included in content of research protocols/proposals. The National Statement includes over 200 statements on requirements of research, including about consent, research design and conduct, governance and review, and considerations for specific populations.

Statements from the NHMRC's *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018) are included below; a 2-3 paragraph response to each guideline is generally expected by research reviewers.

Ethical requirements for research among people in criminal legal system custody are also included below.

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Research merit and integrity

Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable. (NHMRC, 2023, p. 9)

Item	Research content
1.1 (a) How is the research justifiable by potential benefit?	
1.1 (b) Why are methods appropriate to achieve aims?	
1.1 (c) Is it based on current literature or prior studies; or if novel, what rationale is provided?	
1.1 (d) Will the research be conducted or supervised by those with appropriate experience, qualifications and competence?	
1.1 (e) Are facilities appropriate? Are resources adequate?	



Item	Research content
1.2 Has prior peer review judged merit? Has it been approved by, for example, the Aboriginal Health and Medical Research Council in the NSW context?	
1.3 (a) How do researchers demonstrate they are searching for knowledge and understanding?	
1.3 (b) Does the research follow recognised research principles?	
1.3 (c) Are there reasons to suspect the research will not be conducted honestly?	
1.3 (d) How will results, whether favourable or not, be conveyed in a way to permit scrutiny and public understanding?	

Justice

Justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. (NHMRC, 2023, p. 9)

Item	Research content
1.4 (a) Are selection, exclusion and inclusion of participants fair and described accurately?	
1.4 (b) Is recruitment fair?	
1.4 (c) Is there too great a burden on participants?	
1.4 (d) Is there fair distribution of benefits of participation?	
1.4 (e) Are participants exploited?	
1.4 (f) Is there fair access to the benefits of the research?	
1.5 Will research outcomes made accessible to participants in a timely and clear way?	

Beneficence

Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work. (NHMRC, 2023, p. 9)

Item	Research content
1.6 Do the benefits to the participants and/or wider community justify any risks of harms or discomfort to participants?	
1.7 (a) Does research design minimise harm and/or discomfort?	
1.7 (b) Are benefits and risks clarified for participants?	
1.7 (c) Is the welfare of participants supported in the research context?	
1.8 If there are no likely benefits to participants, are the risks lower than would be ethically acceptable when there are such likely benefits?	
1.9 Should the research be suspended if risks are not justified by benefits?	

Respect

Respect for human beings is the common thread through all the discussions of ethical values. (NHMRC, 2023, p. 9)

Item	Research content
1.10 Will the research show due regard for the welfare, beliefs, perceptions, customs and cultural heritage of participants?	
1.11 Will there be respect for privacy, confidentiality, cultural sensitivities and any agreements made?	

Guidelines respecting Aboriginal and Torres Strait Islander peoples

Six core values – spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility – are important to all Aboriginal and Torres Strait Islander peoples. They ensure all human research undertaken with Aboriginal and Torres Strait Islander people and communities:

- respects the shared values of Aboriginal and Torres Strait Islander peoples*
- is relevant for Aboriginal and Torres Strait Islander priorities, needs and aspirations*
- develops long-term ethical relationships among researchers, institutions and sponsors*
- develops best practice ethical standards of research. (NHMRC, 2018, p. 3)*

Item	Research content
How does the research demonstrate spirit and integrity? (p. 4)	
How does the research demonstrate respect for cultural continuity? (p. 4)	
How does the research demonstrate equity with respect to Aboriginal and Torres Strait Islander peoples? (p. 6)	
How does the research demonstrate reciprocity? (p. 7)	
How does the research demonstrate respect for Aboriginal and Torres Strait Islander peoples? (p. 9)	
How does the research demonstrate the value of responsibility in relation to Aboriginal and Torres Strait Islander peoples? (p. 11)	
How does the research demonstrate that rights to traditional knowledges and cultural expressions of Aboriginal and Torres Strait Islander people are respected, protected and maintained? (p. 18)	

For people in custody

Item	Research content
Can people in custody autonomously make decisions to participate? Or not? And withdraw if they wish?	
Do people in custody with low vision, hearing loss, traumatic brain injury, mental illness and/or compounding issues require support to consent to participate?	
Are all documents readable for people in custody?	
Has the participant information sheet adequately addressed the risk of discussing illegal activities or having them arise?	
Will results be available to people in custody if they are released from custody during the study period?	
Are there implications of movement of people in custody between centres?	

References

National Health and Medical Research Council. (2023). National Statement on Ethical Conduct in Human Research. Canberra: Commonwealth of Australia. Retrieved from <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023>

National Health and Medical Research Council. (2018). Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. Canberra: Commonwealth of Australia. Retrieved from <https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities>

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