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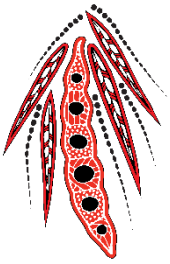

Ethical health research planning kit

September 2022
V4

Girra Maa Indigenous Health Discipline
Megan Williams

Contents

Acknowledgement of Country

I acknowledge the Gadigal of the Eora nation on whose land the writing of this document occurred. I acknowledge ancestors and spirits of this land, Elders of the past and Elders of the present for their enduring custodianship and unceded rightful ownership.

Acknowledgements

This document provides information about the ethical conduct of research in Australia, with examples provided in the New South Wales context.

Thank you to Dr Mark Ragg, Mr Ian Close, Professor Julia Bowman and Ms Victoria Bell of the Justice Health and Forensic Mental Health Network Human Research Ethics Committee and Ms Sally Fitzpatrick from University of Newcastle for their support and contributions to items in this document.

Thank you to the UTS Faculty of Health Indigenous Strategies Committee for their review and endorsement of the material in this document.

Introduction

This document provides a range of information for designing ethical research about the health and wellbeing of Aboriginal and Torres Strait Islander people, the Indigenous First Peoples of Australia. It is current as at August 28 2022. Material is general and for all – whether researchers are Aboriginal and Torres Strait Islander people or of other cultures.

Ensure that you check with the institutions supporting your research about the ethics applications and clearances they require, in the specific location/s of the research, in relation to your role/s e.g., as a staff member or as a student, or both, and how they facilitate applications and clearances. This document does not include information about specific site requirements – they are too diverse and require purposeful inquiries close to the time you seek to make an application.

This document also does not include material about researcher positionality, methodology, methods or data collection are not included here – the focus is on administration items necessary to apply for clearance to conduct research.

Thus, this document is premised on research teams already having engaged with Aboriginal and Torres Strait Islander organisations and Aboriginal and Torres Strait Islander community members to design research, or have plans to do so; as you will see below, research is to be based on Aboriginal and Torres Strait Islander peoples' research priorities.

This document responds to 'frequently asked questions' about Indigenous health research including:

- *Why do I need to meet Aboriginal and Torres Strait Islander health research ethics guidelines if I didn't intend to have Aboriginal and Torres Strait Islander people over-represented in my study?*

- *What is the difference between research and quality assurance?*
- *What ethics applications do I have to make?*
- *Whey are there so many different types of applications and principles?*

This document also includes templates for research planning and ethics applications, an exemplar participant information sheet, and a timelines, budget and research outputs template.

These are all based on my own researcher and HREC membership and chairperson experience, provided for practical support, to be used and adapted across different projects and settings if possible and where needed.

For any updates of feedback contact Megan.Williams@uts.edu.au

Is it research?

The first question to ask is about the definition of research. The National Health and Medical Research Council (NHMRC) *National Statement on ethical conduct in human research* (NHMRC, 2018a) says:

> There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers. (p. 6)

It also says:

> Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:
>
> - taking part in surveys, interviews or focus groups
> - undergoing psychological, physiological or medical testing or treatment
> - being observed by researchers
> - researchers having access to their personal documents or other materials
> - the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath
>
> - access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database. (NHMRC, 2018a, p. 7)

See https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Is it low or negligible risk research?

No research involving Aboriginal and Torres Strait Islander people can be considered low or negligible risk, in accordance with the National Statement (NHMRC, 2018a, p. 61). Similarly, no research with the following populations can be considered lor or negligible risk:

- women who are pregnant and the human fetus
- people with a cognitive impairment, an intellectual disability or a mental illness
- people who may be involved in illegal activities
- people in custody.

Aboriginal and Torres Strait Islander people are currently over-represented in some of the above population groups.

Which committee/s do I apply to?

Given all research with Aboriginal and Torres Strait Islander people is considered high risk, whether we agree with that or not, applications for ethical review should only be made to registered Human Research Ethics Committees (HRECs). That is, ethical clearance can only be provided by HRECs.

For a full list of NSW HRECs and their meeting dates, see: https://www.medicalresearch.nsw.gov.au/ethical-scientific-review/

In NSW, for example, the Office of Health and Medical Research provides support to public health organisations' HRECs as well as researchers. See: https://www.medicalresearch.nsw.gov.au/

If neither you nor your colleagues are affiliated with a university, and your research focuses on Aboriginal and Torres Strait Islander people, you can apply directly to the Aboriginal Health and Medical Research Council of NSW (AH&MRC) HREC (see https://www.ahmrc.org.au/). Its Submittable Application Manager, form and ethics guidelines are included further below.

If you or your colleagues are affiliated with a university, apply to them first as your 'home' or principal HREC. This can relieve pressure on Aboriginal and Torres Strait Islander community controlled HRECs that are under-funded compared to need and requests for reviews. The home university will review and feed back about errors and ethical implications first, and these should include in relation to the NHMRC's Aboriginal and Torres Strait Islander health research guidelines – they are guidelines for all researchers and HRECs to use.

You may wish to enquire, however, about whether the HREC has experience of research with Aboriginal and Torres Strait Islander people, and using the Aboriginal and Torres Strait Islander health research guidelines. Inexperience can lead to errors and complications, and asking about extent of experience need not be threatening but is instead informative about how to best proceed.

On the other hand, some universities will require research that focuses on Aboriginal and Torres Strait Islander people to be first cleared by an Aboriginal and Torres Strait Islander community controlled HREC such as the AH&MRC in NSW before they will consider reviewing an application. This can be because universities have very small numbers of Aboriginal and Torres Strait Islander health research staff or staff with experience in Aboriginal and Torres Strait Islander health research. Or, they seek community clearance as a type of endorsement before their review.

There are also a range of government research committees, community-based interest groups and organisational committees who require their approval before research can be conducted. This might be construed as ethical review, and in practice it may well be, however, according to national guidelines, ethical review must be by a registered HREC. It is important to understand and clearly document exactly what those types of non-HREC committees are reviewing and approving, in what timeframe they will review, with what mandate, and what ongoing reporting and re-application requirements.

Is it exempt from review?

According to the NHMRC (2018a), Quality Improvement (QI) and Quality Assurance (QA) projects or activities that monitor, evaluate or improve the quality of care delivered by a service provider, for individuals or services generally do not require HREC applications or clearances.

QI and QA activities include, for example, reviews of information flow, designing data collection and data recording processes, evaluation and workforce development. They might also help improve environments and settings to which QI or QA data relate (NHMRC, 2014, p. 3)

These may include some of the same processes and methods used in research, including surveys and observation.

In deciding if an activity is QI or QA and if HREC clearance is required, the NHMRC provide several prompts and considerations, as do NSW Health, in:

- *NHMRC's ethical considerations in quality assurance and evaluation activities* developed by the Australian Health Ethics Committee in 2014 and available at https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities

- *NSW Health's quality Improvement & ethical review: A practice guide for NSW* https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2007_020.pdf

Considerations from these are:

- What the possible risks and burdens to participants might be
- What consent might be needed from participants, and information to support their decision making
- Privacy and data security needs
- Any legislative requirements
- National and professional standards.

Triggers for ethical review are to also be considered, which include:

- Whether there is potential to infringe privacy or professional reputations
- whether there will be any secondary use of
- If data will be collected from participants beyond what it will be collected routinely
- Whether any testing will occur of non-standard protocols or equipment
- Comparison or randomisation of cohorts or use of placebos
- Targeted analysis of data involving minority or vulnerable groups that will be separated out from the main QA or QI activity.

NSW Health's document provides a checklist – see Appendix A – about issues that may require consent, or that have privacy and confidentiality implications.

Overall, the NHMRC is clear that 'those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy' (NHMRC, 2014, p. 2) as the main consideration of whether an HREC clearance should be sought.

Some institutions have processes for advising on and approving QI and QA activities.

QA and QI activities are routinely conducted in Aboriginal and Torres Strait Islander community-controlled health organisations, and without HREC clearances. They usually have project governance structures and report to a community-based board of directors.

One deciding factor can be the intended use of QA and QI information. If reporting using data collected is to be among external audiences, HREC clearance is advisable. Otherwise, according to the NHMRC (2014), data from QI and QA are only to be used internally by the organisation doing the QI or QA.

Why do I need to meet Aboriginal and Torres Strait Islander health research ethics guidelines?

Most, if not all health research in NSW is considered to be of interest to Aboriginal and Torres Strait Islander people living in NSW. Aboriginal and Torres Strait Islander people are usually present in all data about health and wellbeing. Even though Aboriginal and Torres Strait Islander people are a minority population in NSW, we are often over-represented in data on health issues, and often also have an interest in using available health research.

Research teams focussing on whole-of-population studies or studies of specific populations e.g., young people, often do not intend to target or specifically include Aboriginal and Torres Strait Islander people. They may assert that the *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders* do not apply to them.

The following material from the NHMRC's National Statement (2018a) reinforces why these guidelines do apply.

The text on page 78 of the National Statement is a useful beginning:

> 4.7.6 Where:
>
> (a) the geographic location of the research is such that a significant number of the population are likely to be Aboriginal and Torres Strait Islander, and/or
>
> (b) the research is focused on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander Peoples and the population base has a significant proportion of Aboriginal and Torres Strait Islander people, the research should provide fair opportunity for involvement of Aboriginal and Torres Strait Islander Peoples… (NHMRC, 2018a, p. 78)

In relation to point (a) a location could be a hospital or health service setting, or prison, for example, where Aboriginal and Torres Strait Islander people are a 'significant number' with significance here understood as including being disproportionately over-represented, beyond actual number. This is extended in point (b) above.

More directly, the NHMRC (2018a) say that

> researchers planning to do any type of research involving Aboriginal and Torres Strait Islander peoples must consult and follow the advice in the most contemporary versions… (p. 22)

… of guidelines documented by the NHMRC and by the Australian Institute for Aboriginal and Torres Strait Islander Studies.

The NHMRC (2018a) on page 29 of the National Statement say,

> 3.1.16 Researchers and reviewers should consider the degree to which potential participant populations might be over-researched or may require special consideration or protection and the degree to which the flow of benefits to that population (or to individual participants) justify the burdens.
>
> Equally, people should not be denied the opportunity to exercise self-determination or obtain the potential benefits of research solely because they are a member of a population that might be over-researched or may require special consideration or protection, such as Aboriginal and Torres Strait Islander peoples.

These points mean that special considerations should be taken by researchers to really think about who the participants of their research will be, and how to ensure justice and beneficence with demonstrable merit and integrity.

That is, the NHMRC understand that the conduct of all research should take into consideration needs of Aboriginal and Torres Strait Islander people. The following statement by the NHMRC (2018a) on page 29 of the National Statement, about research in general, concurs:

> 3.1.17 The recruitment strategy must be respectful of potential participants and their culture, traditions and beliefs and facilitate their voluntary participation.

This quote is for all researchers, and all of their research. So too is the following, (NHMRC, 2018a, p. 30):

> Well-designed consent strategies are [to be] appropriately tailored to the potential participants, the research design, the topic and the context.

The NHMRC are cognisant of the impacts of health research on Traditional Custodians of Australia, and on page 38 of the National Statement indicate:

> The approach taken to communicating findings and results should reflect principles of good science and adhere to the ethical principles of justice, respect and beneficence discussed in Section 1, including consideration of the values and preferences of traditional custodians, such as Aboriginal and Torres Strait Islander peoples. (NHMRC, 2018a, p. 38)

The following quote from the National Statement particularly directs national and multi-centre research to be inclusive:

> 4.7.1 The researcher should ensure that research methods are respectful and acknowledge the cultural distinctiveness of discrete Aboriginal and Torres Strait Islander communities or groups participating in the research – including national or multi-centre research. (NHMRC, 2018a, p. 78)

The NHMRC (2018b, p. 13) also state that in the document *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders* that these guidelines:

> apply to all research with Aboriginal and Torres Strait Islander people and communities.

The NHMRC does not discuss exemptions or ways national or multi-centre research should overlook or not take Aboriginal and Torres Strait Islander people into consideration. Instead, the NHMRC says in their Aboriginal and Torres Strait Islander health research guidelines that:

> The Guidelines should inform all steps in the research process including conception (the initial idea), design (planning the research), conduct (ways of doing the research), reporting (what happened), and dissemination of findings (circulation to relevant bodies). The Guidelines apply to all researchers, whether they are Aboriginal or Torres Strait Islander people, other Australians or international researchers. (NHMRC, 2018b, p. 13)

Overall, the NHMRC (2018a):

> seek to ensure that research with and about Aboriginal and Torres Strait Islander peoples follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research. (p. 22)

Further, the NHMRC require engagement with jurisdictional and local Aboriginal and Torres Strait Islander research protocols and HRECs.

As stated earlier, any research relevant to the health and wellbeing of Aboriginal and Torres Strait Islander people in NSW must make an application to and receive clearance to proceed from the NSW Aboriginal Health and Medical Research Council's (AH&MRC) HREC at https://www.ahmrc.org.au/ (and see information further below).

The AH&MRC are clear also about their role in assessing research and its relevance and benefit to Aboriginal and Torres Strait Islander people in NSW. In their Secretariat Standard Operating Procedures manual, there are five criteria endorsed by the NSW Ministry of Health – Office of Health and Medical Research under policy directive (PD2010_055; AH&MRC, 2020) under which an application MUST be submitted to the AH&MRC HREC.

They say approval from the AH&MRC HREC is required where the research project involves research in, or concerning, NSW AND any of the following apply:

1. The experience of Aboriginal people is an explicit focus of all or part of the research
2. Data collection is explicitly directed at Aboriginal peoples
3. Aboriginal peoples, as a group, are to be examined in the results
4. The information has an impact on one or more Aboriginal communities
5. Aboriginal health funds are a source of funding.

See page 8 of https://www.ahmrc.org.au/wp-content/uploads/2021/02/9-AHMRC_NSW-Aboriignal-Health-Ethics-Guidelines-Key-Principles-2.pdf

In essence, Aboriginal and Torres Strait Islander people must lead the conceptualising, design and conduct of research, as well as analysis, interpretation, translation, reporting and distribution of findings. Research must at least have oversight by a fully remunerated Aboriginal and Torres Strait Islander Advisory Group, as well as have Aboriginal and Torres Strait Islander staff and a plan to build the capacity of people of other cultures involved to engage respectfully with Aboriginal and Torres Strait Islander people, knowledges and protocols.

NHMRC guidelines for ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities:

As above, 'researcher planning to do any type of research involving Aboriginal and Torres Strait Islander peoples must consult and follow' the NHMRC's Aboriginal and Torres Strait Islander health research guidelines (2018a, p. 24).

Adherence must occur through demonstration of action, and a written description about this action, able to be provided when first applying for ethical review clearance, as well as in annual reports.

If you'd like examples of research projects that have been cleared by HRECs as successfully meeting these, do feel free to contact me and ask:

megan.williams@uts.edu.au For now, I've added a few dot points from the NHMRC about expectations of these guidelines in action.

There are clear examples also in the NHMRC document Keeping Research on Track II. It's a community guide and clearly written https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii, as is the previous version (though rescinded) which is perhaps even more easily understood https://www.nhmrc.gov.au/about-us/publications/keeping-research-track

1. **Responsibility:**

    - A core value in the lives of Aboriginal and Torres Strait Islander people, with all having a role in caring for Country, other people and spiritual connections, including researchers
    - Ensuring researchers are accountable to Aboriginal and Torres Strait Islander individuals, families and communities
    - Aiming for harmony between Aboriginal and Torres Strait Islander rights, the science of research, trust of the community for research and the agreed benefits of research.

2. **Reciprocity:**

    - Designing research so that Aboriginal and Torres Strait Islander Communities define how the research will benefit them
    - Benefits can be in information, opportunities or outcomes, to advance the interests of Aboriginal and Torres Strait Islander people.

3. **Respect:**

    - Self-awareness by researchers of how they impact on the research, to then try to see how their behaviour and research might impact on Aboriginal and Torres Strait Islander communities over time
    - Developing trust of Aboriginal and Torres Strait Islander people for the researchers, and clear, mutual agreements about the research.

4. **Equity:**

    - Valuing Aboriginal and Torres Strait Islander people's individual and collective knowledge, wisdom and resources
    - Using these to bring about the fair distribution of benefit from Australia's resources to achieve equity in health, legal, economic and social status of Aboriginal and Torres Strait Islander people.

5. **Cultural continuity:**

- Focussing on the way Aboriginal and Torres Strait Islander culture is about the individual as well family and community, so, doing research that includes those perspectives

- Doing research to understand the distinctiveness of Aboriginal and Torres Strait Islander culture/s.

6. **Spirit and integrity:**

    - Respecting the ongoing connection between past, present and future generations, and carrying out the other five values listed above.

Points above need to be clearly addressed in writing and are best uploaded as a separate document to all HREC applications.

These guidelines get met in addition to written statements being made about how to achieve the guidelines/principles of any Aboriginal and Torres Strait Islander ethics committees or community organisations. Answer each and every one separately and specifically because they are all different – the local committees self-determining as per their right what is required of researchers and research.

The National Statement ethics statements listed below are not usually so clearly written about – material about them needs to skilfully get woven into research design text to show how they are met. Read on below… Some researchers do also use the templates below to keep track of their projects and ethics considerations.

National Statement ethics checklist

Research design, the Research Protocol and the Human Research Ethics Application (HREA) are to be based on Australia's *National Statement on Ethical Conduct in Human Research Guidelines for Research* at https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.

Items in the National Statement are not clearly and directly prompted for in the HREA. Other university and community research application processes also generally do not have ways for researchers to demonstrate alignment with the National Statement. Further, the HREA and other research applications may not include a way for researchers to show they meet Aboriginal and Torres Strait Islander health research guidelines.

It is the work of the researcher to ensure their research design and descriptions of their research match and operationalise the National Statement ethical requirements. Researchers must write their Research Protocol and HREA answers to demonstrate within text how their research aligns – clear statements about how guidelines are met, with evidence where possible. the wording of the following items can be used, and transformed into sentences that provide examples relevant to your research project.

Qualifications and experience of researchers

The following require details and evidence of critical self-reflection among the research team:

Item	Research content
1.1 (e) Will the research be conducted or supervised by those with appropriate experience, qualifications and competence?	
1.1 (f) Are facilities appropriate? Are resources adequate?	

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, 2007, updated 2018a, p. 9)

Merit

NS item	**Relevant 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?	
1.2 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 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, 2007, updated 2018a, 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) Are there any benefits to the participants? Is the presence or absence of benefit described clearly?	
1.4 (e) Are participants exploited?	
1.4 (f) Are the benefits of the research distributed fairly?	
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, 2007, updated 2018a, p. 9)

Item	Research content
1.6/1.8 Do the benefits to the participants and/or wider community justify any risks of harms or discomfort to participants? Note that if no benefits are likely for participants, risks to participants should be low.	

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?	

Respect

> *Respect for human beings is the common thread through all the discussions of ethical values.* (NHMRC, 2007, updated 2018a, p. 9)

Item	**Research content**
1.1 (d) How does the research design ensure respect?	
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?	
3.1.40 Could participants be identified?	
3.1.41 (b) Are identifiers and content stored separately?	
3.1.41 (c) To reduce the risk of identifiability, have the roles of those responsible for management of identifiers been separated from the roles of those responsible for analysing content?	
3.1.45 Are there plans for the management, storage, retrieval and destruction of data? Has a data custodian been identified?	

Consent

> *Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'*. (NHMRC, 2007, updated 2018a, p. 16)

Item	Research content
2.2.1 Is participation voluntary?	
2.2.1 Will participants understand both the research, and implications of participating in it?	
2.2.2 Will participants understand the purpose of the research and its methods?	
2.2.3 Is the information presented in suitable way for each participant? Is it likely to be readable by all participants? Can it be discussed with participants, in their language, for those with low literacy or who speak a language other than English?	
2.2.4 Is there an opportunity to ask questions?	
2.2.6 Is information provided separately on: … the consequences of not participating?	
… how the research will be monitored?	
… contact details of the researchers?	
… contact details of the person to receive complaints?	
… how privacy and confidentiality will be protected?	
… the participant's right to withdraw at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data?	
… the amounts and sources of funding for the research?	
… financial or other relevant declarations of interests of researchers, sponsors or institutions?	

Item	Research content
… the likelihood and form of dissemination of the research results, including publication?	
… any expected benefits to the wider community?	
… any other relevant information?	
1.12/1.13 If participants are unable to make their own decisions or have diminished capacity to do so, how do researchers empower or protect them?	

For people in institutions

Item	Research content
Are there implications for institution staffing e.g. to assist in data collection?	
Can people in custody autonomously make decisions to participate? Or not? And withdraw if they wish?	
Do people 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 institutions e.g. without assistance, and within constraints?	
Has the participant information sheet adequately addressed the risk of discussing illegal activities or having them arise?	
Will results be available to people in institutions they are released from custody during the study period?	
Are there implications of movement of people between institutions?	

Relevant to administration

Item	Comments
Do the protocol, the HREA and all other documentation match? What additional information or explanations should be conveyed, if any?	

How do I apply for clearances?

Be as informed as possible about application processes, timeframes and review requirements from the main institution HREC clearance is sought from. As a research team, also develop a clear understanding of all aspects of the research project before beginning the application.

Most, if not all HRECs require applications to be made online. The portals and processes all differ.

Most use the Human Research Ethics Application (HREA), but not all, so do check.

If possible, obtain a Word version of the exact online application. If not possible, create this using specific questions used in the online application. Working offline enables teams to prepare draft application versions, using several rounds of feedback to come to a shared agreement among all named team members. This is essential for proofreading, removing unnecessary overlap in information and providing clear, accurate and consistent details throughout.

The HREA, for example, is to be a stand-alone document full of complete information on which the values of the NHMRC about ethical research can be assessed. That is, it is beyond a description of the research methods, and instead ethical values must also be demonstrated throughout text.

Information about the HREA included further below, including the full application form template for completion in Word.

First however, it is essential to complete a Research Protocol – see further below.

What is the National Mutual Acceptance Scheme?

Most HRECs will accept an application approved by another HREC because of the National Mutual Acceptance Scheme (NMAS). However, it is important to check, because some HRECs are exempt. Many Aboriginal and Torres Strait Islander HRECs and those for people in prison, for example, are NMAS exempt. They will require a new application made to them in addition to the primary HREC such as a university-based committee, and all the other HRECs.

Committees exempt from the NMAS can serve as a primary committee.

See here for information in the NSW context:
https://www.medicalresearch.nsw.gov.au/ethical-scientific-review/

What should be included in a research protocol?

The following topics are ideal to write about when drafting a stand-alone Research Protocol document, also called a research plan. This should be completed before the HREA or other equivalent HREC application form.

The Research Protocol builds on, for example, applications for funding. It is to be submitted in addition to the HREA or other HREC research application form required.

The following are suggested fields for a Research Protocol, a type of template. Add and remove topics as needed.

Please note, do not write in italics; italics are here to signify what is suggested to write about. Write in plain text e.g. Arial 10-12 size font, Times New Roman 12 or Calibri 11-12.

Title
Formal title that identifies topic, participant group, location and methods if possible

Working title
E.g. if acronym or short form used

Keywords
3-5, suggesting cross-disciplinarity

Abstract
Anywhere between 100-250 words; no references required

Plain language description
School year 5 English readability; feedback essential from the readership audience.

Team
Identify whole team

- *Title*
- *Name*
- *Post-nominals*
- *Workplace*
- *Qualifications*
- *Role*

2-page CVs are often required for each team member.

Governance
Discuss how Aboriginal and Torres Strait Islander people lead and are involved in the project, particularly decision making, data collection,

interpretation and conveying of findings. Use a diagram if there are multiple project teams and processes.

Resources
Funding source/s; interests other parties have in the data; budget, in-kind contributions, infrastructure details as appropriate – to help confirm feasibility of the project.

Aim
A clear statement of the overall aim of the project.

Hypothesis
Only if relevant and different to aim, and for quantitative or mixed-methods research.

Objectives
Key concepts to help meet the aim. These may cross-over, replace, or be replaced by research questions below.

Research questions
Three to five questions to ask of the literature, and through data collection.

Significance
Brief statement that introduces the problem, and the solution this project proposes

Project development
How has the project been developed? Who has been involved, including current and potential partners? Build credibility.

Background
Problem statement; introduce research topic with brief outline of the context and rationale for the study, and the team members.

Methodology
Outline key concepts in the framework informing the research e.g., from theoretical and philosophical perspectives. Use references and a diagram if content is complicated.

Methods
Include the following as relevant:

- *Proposed data collection processes*
- *Population characteristics overview, sample size, justification*
- *Administrative data sets required*
- *Resources required to support recruitment of e.g. research partners, correctional centres, community*
- *How population will be identified*
- *Recruitment – who will do it, how, when*
- *Inclusion criteria*
- *Exclusion criteria*

- *Informed consent process – who, how, when.*

Use a flowchart or diagram if multiple methods are used and over time.

Incentives to participate
Detail and justify, and identify timing and process of allocation

Confidentiality
Outline how confidentiality of research participants will be maintained. Will people be identifiable?

Risks
Identify all possible risks of the research for participants and the team, Demands on time, locations
- *Disclosures eg crime and harm to self and others*
- *Inconvenience*
- *Personal experience e.g. discomfort.*

Identify how likely risks are to occur.

Identify how risks will be prevented and/or addressed e.g.:
- *Staff training and skills*
- *Referral sheets for participants*
- *Follow-up*
- *Staff debriefing and support.*

The above in table format within a document or as appendix is suitable.

Written statement required to justify why benefits outweigh risks.

Data analysis
- *Theory and framework guidance*
- *Techniques for analysis*
- *Resources required to support analysis of e.g. research partners, correctional centres, community*
- *Reducing and cleaning data*
- *Collaboration with others including Aboriginal and Torres Strait Islander people*
- *Computer-aided analysis packages to be used*
- *Interpretation of findings including by Aboriginal and Torres Strait Islander people.*

Data handling
Data storage, transfer and sharing including how these safeguard confidentiality.

Ethical implications
Including reflection on NHMRC and other guidelines, and how they will be managed and addressed.

Research translation and knowledge transfer
How to convey learnings to and with community, policy makers and other researchers, when and how?

Outputs
Identify e.g., community feedback, peer-reviewed publications, social media communications, occasional papers, online articles to be produced, and by who, when, how, with what resources. See example table further below.

Timeframe
Commencement and end dates; use a table or visual aid e.g., a matrix with month or quarter, and task. Purpose is to convey feasibility and integrity of the project, team and resources over time. See example further below.

Contact details
Person to receive inquiries and HREC replies.

Document version and date
Insert at top of document clearly, and as footer; new updated details required on all versions produced.

What goes into a Human Research Ethics Application?

All the fields below are from the online Human Research Ethics Application (HREA) accessed in NSW through the NSW Government's Research Ethics & Governance Information System (REGIS; see https://regis.health.nsw.gov.au/) for public health organisations in July 2022. This is the form that most HRECs require researchers to use, accessed through e.g., university portals. Do note that some HRECs have different forms – ensure you access exactly what you require for your project.

This HREA version is provided here to improve planning for and quality of applications to HRECs. It is advisable to complete all HREA fields in Word or the like first before entering material in the online HREA portal. This reduces risks of internet dropouts and data losses, ensures all content can easily be affirmed by all people named on the application, and ensures all spelling, grammar and other errors can be removed.

A well-written HREA relies on a good quality Research Protocol being already finalised, with agreement on its contents from whole research team and key stakeholders; a separate Research Protocol template is available if required.

As stated above, research design, the Research Protocol and the HREA are to be based on Australia's *National Statement on Ethical Conduct in Human Research Guidelines for Research* at https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 (a separate checklist is available). It is the work of the researcher to ensure their research design and descriptions of their research match and operationalise the NS ethical requirements – the ethics statements are not overtly asked about or necessarily directly answered in the HREA.

It is advisable for research teams to discuss answers to all questions in the HREA (included here), to consider ethical issues and avoid one researcher attempting to answering in isolation.

The HREA uses a cascading effect for answering questions. That is, the way some questions are answered changes the form to open out additional fields to be completed. The below version of the HREA includes all possible fields. Not all will be relevant to you. Add text such as 'not applicable' where relevant in your Word version and ensure attention to detail when completing the online form for accuracy at that time.

Ensure error-free, accurate alignment of all your written material across your Research Protocol, HREA, Participant Information Sheets and Consent Forms (separate examples available), data collection tools and all other study material before uploading online.

The HREA fields

Application Management Information – *some fields auto-generated*
Application ID:
Created date:
Originating Application ID:
**This is the earliest application from which this application (XXXXXX) was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application (XXXXXXX) was copied.*
Version Number: 1
Application submitted to:

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Q1.1 Project Title:

Q1.2 Summary of the research project:

Q1.3 Which category/ies of research best describes the project?

Q1.4 In what environments will the research be conducted?

Q1.5 What organisation/entity has overall responsibility for this project?

Q1.6 Describe how this research project is currently, or will be, funded.

Q1.7 Anticipated starting date of the research project:

Q1.8 Anticipated duration of the research project:

Project Team

Name:

Q1.9.4 Email Address:

Q1.9.5 Is this person the contact person for this application?

Yes

Q1.9.5.1 Email Address:	
Q1.9.5.2 Telephone Number:	
Q1.9.5.3 Mailing Address	

Q1.9.6 Is this person a student on this project?

Q1.9.6.1 Supervisory arrangements, support and training to be provided:

Q1.9.6.2 Educational program undertaken for this project:

Q1.9.7 Institutional affiliation and position:

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)***:**

Q1.9.10 Position on the research project:

Q1.9.12 Research activities XXX will be responsible for:

Q1.9.13 Expertise relevant to the research activity:

Name:

Q1.9.4 Email Address:

Q1.9.5 Is this person the contact person for this application?

Q1.9.6 Is this person a student on this project?

Q1.9.7 Institutional affiliation and position:

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)***:**

Q1.9.10 Position on the research project:

Q1.9.12 Research activities XXX will be responsible for:

Q1.9.13 Expertise relevant to the research activity:

Disclosure of interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

Q1.11.1 Detail the restrictions or limits on publication of data arising from the research project and explain how these will be balanced with relevant accessibility expectations.

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated?

Q1.12.1 What was the review process and what was the outcome?

Q 1.12.2 Attach evidence of the outcome of the scientific or academic review process. *(optional)*

Q1.13 Has this research project had prior ethics review?

Q1.14 Will any further or additional specialised review of this application be sought?

Q1.14.1 Name of entity conducting specialist review	Q1.14.2 When review will be sought

Setting of research

Q1.15 Will this project be conducted at multiple sites?

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?

Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

Research Method	Status
Action research	
Biospecimen analysis research	
Data linkage research	
Ethnographic research	
Epidemiological research	
Interventional/Clinical Trials research	
Observational research	
Survey/Interview/Focus Group research	
Textual analysis research	
None of the above	

Q1.18 The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	
Human biospecimens only	
Data associated with human beings only (i.e. as the primary object of research)	

Q1.18.1 Does your research involve the prospective collection of data?

No

Q1.19 The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	
Children and young people	
People highly dependent on medical care who may be unable to give consent	
People with a cognitive impairment, intellectual disability or mental illness	
People in dependent or unequal relationships	
People who may be involved in illegal activities	
People in other countries	
Aboriginal and Torres Strait Islander peoples	

Method Specific Questions

Survey/Interview/Focus Group Research

M8.1 What process/es will your research project use?

M8.2 How will you engage with your participants?

M8.3 How will personal identifiers be retained or removed over the course of your project?

M8.4 Will participants have the opportunity to review or edit their responses or contributions prior to data analysis or publication?

M8.4.1.1 Indicate the relevant section/s of your Project Description that detail this opportunity.

M8.5 Is it foreseeable that your project will explore topics that may cause distress for participants?

Participant Specific Questions

Women who are pregnant and the human fetus

P1.1 Who will the research involve?

P1.1.1 Explain why there are no suitable alternatives by which the aims of the research can be achieved, as required by National Statement 4.1.12.

P1.2 Is there a foreseeable impact on the fetus in utero?

See the Risk Section of this HREA for more details.

P1.3 How will the wellbeing of the pregnant woman and fetus be managed?

P1.4 Describe any arrangements for counselling that will be provided or made available to the women.

P1.5 How will you ensure that the research meets the guidance provided in National Statement 4.1.20 regarding the information that should be provided to female participants?

P1.6 Will the research involve the removal of organs or tissues from fetuses that have been delivered dead?

P1.6.1 How will you ensure that the research meets the guidance provided in National Statement 4.1.22 regarding the removal of organs or tissue from a fetus?

P1.7 Will fetal cells be derived from fetal tissue and stored or propagated, or will the tissue or cells be used for human transplantation?

P1.7.1 How will you ensure that the research meets the guidance provided in National Statement 4.1.23 regarding obtaining consent for this derivation or use?

Children and young people

P2.1 How will the children or young people participate in this research?

P2.2 Explain how the research is likely to advance knowledge about the health or welfare or other matters relevant to children or young people.

P2.3 Explain whether children's or young people's participation is indispensable to the conduct of the research.

P2.4 How will you ensure that the children or young people's safety, emotional and psychological security and wellbeing are protected?

P2.5 How will you establish that participation in the research is not contrary to the best interests of the children or young people?

People highly dependent on medical care who may be unable to give consent

P3.1 Who will the research involve?

P3.2 Describe how the research will be minimally invasive or provide a therapeutic benefit that is related to the participants' condition.

P3.3 Describe how the research will lead to increased understanding about, or improvements in, the care of people receiving this type of medical care or who are in this condition.

People with a cognitive impairment, intellectual disability or mental illness

P4.1 Who will the research involve?

P4.2 How will the research project accommodate people with a cognitive impairment, an intellectual disability or a mental illness?

P4.3 How will the participants' degree of cognitive impairment, intellectual disability or mental illness be assessed?

P4.4 How will you assess whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to discomfort or distress?

People in dependent or unequal relationships

P5.1 Describe any potentially detrimental effects on people in dependent or unequal relationships who may participate in your research, and how will you manage them.

People who may be involved in illegal activities

P6.1 Is the research designed to discover or expose illegal activity?

P6.1.1.1 Although the research is not designed to discover illegal activity, is it likely or foreseeable that illegal activity will be discovered?

P6.2 Will you or your institution have a legal duty to disclose information about illegal activity that is discovered?

P6.2.1 How will the duty to disclose this information be managed?

P6.3 Will you have contact, in a professional role, other than as a researcher, with people who may be involved in illegal activities?

P6.3.1 How will you ensure that the research is not be compromised by contact in that professional role and that obligations to participants related to that role will not be compromised by the research?

P6.4 Will the research involve participants who are subject to criminal justice processes?

People in other countries

P7.1 How will local cultural values be acknowledged and reflected in both the design of the research and the conduct of researchers?

P7.2 How will the design of the research take into account local power relations, inequalities and divisions?

Provide the following details for each country in which the research project will be conducted.

P7.3.1 Name of the country.

P7.3.2 Is there an ethics review process?

P7.3.2.1 Will the Australian review body's approval of the research need to be reported to a local body?

P7.3.2.2 Identify the local ethics guidelines that will be used for reviewing the research in this country.

P7.4 Describe any factors that may make it problematic to conform to ethical standards expressed in the National Statement and what steps will be taken to address these matters.

P7.5 Do you plan to engage individuals from any country in which the research will be conducted to help conduct the research?

P7.5.1 Who do you intend to engage and how will you employ them?

P7.5.2 How will the capacity and expertise of these individuals to conduct the research be assessed?

P7.5.3 How will you ensure that these individuals conduct the research in a manner that accords participants no less respect and protection than the National Statement requires?

P7.6 To whom will participants direct any questions, concerns or complaints about the research?

P7.7 How will you engage with participants and their communities with respect to their expectations of the research project?

P7.8 How will you manage these expectations in light of any resource limitations of the research project?

Aboriginal and Torres Strait Islander peoples

P8.1 How have you considered and addressed local Aboriginal and Torres Strait Islander cultural values in the design and conduct of this research?

P8.2 Describe the process that will be used to satisfy the requirements for community consultation, engagement and governance that apply to your research?

P8.3 List any relevant ethics guidelines that you have consulted during the development of your research project.

Recruitment Questions

As the research involves *Data associated with human beings only*, no recruitment questions were asked. Any issues related to access to the data and consent to its use initially in the Consent Section and Data and Privacy Section

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Consent Questions

Q2.2.5 Has consent been obtained from participant for the use of their data in the proposed research?

Q2.2.5.2.1 Explain why consent for use (or secondary use) of the data has not been obtained?

(Children and young people specific questions)
Q2.2.P2.1 From whom are you obtaining consent?

Q2.2.P2.2 Will the research involve the participation of any children who are not of sufficient maturity to consent?

Q2.2.P2.3 Explain how the children or young people's capacity to consent will be judged.

Q2.2.P2.4 Describe the form of proposed discussions with children about the research at their level of comprehension.

Q2.2.P2.5 Are you proposing to obtain consent using standing parental consent for the participation of the children or young people?

(People highly dependent on medical care who may be unable to give consent specific question)
Q2.2.P3.1 Will some or all of the participants have impaired capacity to provide consent for participation in the research?

Q2.2.P3.1.1 Are you intending to commence the research without prior consent from the participants or authorised representatives as per National Statement 4.4.13?

Q2.2.P3.1.2 How will you communicate with and obtain consent from the participants' carers, their families, their guardian and/or other responsible persons?

Q2.2.P3.2 Describe how the processes of obtaining consent (or not obtaining consent) is consistent with the process outlined in National Statement 4.4.9-14.

(People with a cognitive impairment, intellectual disability or mental illness specific question)

Q2.2.P4.1 Describe the process that you will use to determine a person's capacity to provide consent to participate in the research if that person has a cognitive impairment, intellectual disability or mental illness.

Q2.2.P4.2 Describe how the process of obtaining consent is consistent with the requirements outlined in National Statement 4.5.5-11 regarding having respect for participants with a cognitive impairment, an intellectual disability, or a mental illness.

(People who may be involved in illegal activities specific question)

Q2.2.P6.1 How will you ensure that participants are aware of the likelihood that illegal activity may be discovered and any duty that you may have to disclose information about illegal activity that is discovered?

Risk Questions

Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.

Q 2.3.2 Describe how these risks will be mitigated and managed.

(People in dependent or unequal relationships specific question)

Q 2.3.P5.1 How will you ensure that a person declining to participate in, or deciding to withdraw from, research will not suffer any negative consequences?

Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?

Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

Personal information
Sensitive information
Health information

Q3.2 Indicate the type of information/data you will be using in this project:

Personal information
Sensitive information
Health information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

Q3.9.1 To whom do you plan to disclose the personal information/data?

Q3.9.2 Describe how you will protect the privacy of the participants and the security of the personal information/data that you will be disclosing?

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

Q3.11.1 Describe how you will explain to participants the restrictions on your ability to give them an assurance of confidentiality.

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

Q3.12.1 Describe any ethical considerations relating to the sharing of individual research results with the participants.

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

Q3.16 Will the outcomes of this project be disseminated to the participants?

Q3.16.1.1 Describe how the outcomes of the project will be disseminated to the participants, or refer to the relevant section/s of your Project Description/Protocol which deals with this matter.

Q3.16.1.2 Describe any ethical considerations relating to any dissemination of outcomes to the participants.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

Section 4 – Attachments and Declarations

Attachments

The following documents have been attached to this HREA.

Project Description/Protocol

See attachment *1 Cover Page.pdf*

Other attachments

Type	Attachment File Name	Attachment Description

Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

☑ Certified

What about Aboriginal and Torres Strait Islander ethics committees?

In addition to submitting a HREA to your relevant local HREC, if your research is of interest to or involves Aboriginal and Torres Strait Islander people, you will require clearance by an HREC of an Aboriginal and Torres Strait Islander community controlled health organisation.

For example, in NSW, an application must be made to the independent registered Aboriginal Health and Medical Research Council of NSW (AH&MRC) HREC. The AH&MRC uses the Submittable online form and has its own key principles to meet, which are different to the NHMRC's. Details of these are below.

As discussed above, some HRECs may require written evidence of clearance by the AH&MRC HREC prior to their HREC either reviewing or endorsing in line with the National Mutual Acceptance Scheme.

As recommended above, complete this form in Word, offline, for collaborative and accurate text writing and editing. When accurate and endorsed by all team researchers, enter material into the online portal, which requires a username and password.

Much of the below information should already be written about in the overall existing Research Protocol or research plan.

There are two ways to go from here. Some researchers write clear statements demonstrating how the AH&MRC's principles are met; they do this as an independent process and independent document, separate to the online Submittable ethics document. That's because negotiation about meeting ethics principles takes time, and different processes to filling in an application for ethics clearance online. If the ethics principles are met and this is demonstrated in writing, then the written text can simply be pasted into the application. Then, it means there is a stand-along document about ethics principles and the principles are not buried within an online ethics application. Some projects are proud to display how they meet ethics guidelines.

AH&MRC principles for NSW

Here are the AH&MRC's principles for health research by, with, about and of interest to Aboriginal and Torres Strait Islander people in NSW. The original numbering is retained below from their document at https://www.ahmrc.org.au/resource/nsw-aboriginal-health-ethics-guidelines-key-principles/

Remember these are guidelines for the NSW jurisdiction only – check in your local area if outside NSW for what you will need to meet.

2.1 Net Benefits for Aboriginal people and communities

The benefits of the research may be for Aboriginal health in general or specifically for the health of Aboriginal people and communities participating in the project. (AH&MRC, 2020, p. 5)

Item	Research content
2.1.1 Co-designing a research project with Aboriginal people and communities will help ensure that it is determined as a priority, a need and is of benefit to the Aboriginal people and communities affected.	
2.1.2 The research addresses and overcomes an identified issue.	
2.1.3 The risks have been identified, assessed, and mitigated.	
2.1.4 There will be a net benefit after considering known negatives and potential risks.	

(Links to the National Statement: 1.1, 1.3, 1.4, 1.6, 1.7, 1.8, 2.1.2, 2.2.2, 2.2.9, 4.7.7 - 4.7.9)

2.2 Aboriginal Community Control of Research

Aboriginal Community Control must be a key focus of all projects affecting Aboriginal people. This means that at all stages of the research project, Aboriginal people and communities participating in or affected by the research will be fully informed about and agree with the purposes and conduct of the project. (AH&MRC, 2020, p. 5)

Item	Research content
2.2.1 It is acknowledged that Aboriginal people have a right to make decisions about research affecting them.	
2.2.2 Aboriginal community involvement, support and consent has been sought.	
2.2.3 There is Aboriginal oversight and meaningful engagement at all stages of the project.	
2.2.4 Formal agreements have been developed with the people and communities affected.	
2.2.5 There is appropriate Aboriginal Governance of all stages of the project.	

2.2.6 Provide communities with all the relevant information and explanations on the intent, process and methodology, evaluation, and potential value of any research proposal.	
2.2.7 Comply with requests for further information from relevant community-controlled organisations associated with the research proposal.	

(Links to the National Statement: 1.3, 1.5, 1.11, 2.2.1, 2.2.2, 2.2.5, 2.2.9, 2.2.19, 2.2.20, 4.7.10 – 4.7.12)

2.3 Cultural Sensitivity

Cultural protocols and community decision making processes will vary between Aboriginal communities, researchers should consider this when designing a project. (AH&MRC, 2020, p. 6)

Item	Research content
2.3.1 Varying community protocols and processes have been considered and adhered to. 2.3.2 Aboriginal community involvement, support and consent has been sought.	
2.3.3 Members of the community affected by the research have been properly consulted with and are informed of the purposes and conduct of the research.	
2.3.4 Outline your Aboriginal consultation and engagement to date.	
2.3.5 Questionnaires, surveys, and other documents must be determined culturally appropriate by the Aboriginal people and communities affected.	
2.3.6 History, colonisation and its ongoing impacts is addressed.	

(Links to the National Statement: 1.10, 1.1(d), 1.5, 1.11, 2.2.19, 2.2.20, 4.7.1 - 4.7.3)

2.4 Reimbursement of costs

There must not be any imposition upon Aboriginal people and communities to be involved in the research project. (AH&MRC, 2020, p. 6)

Item	Research content
2.4.1 Reimbursements may be financial or non-financial; but should be considerate of costs, time and travel incurred by Aboriginal people involved in the project. Knowledge and experience sharing must also be considered as a valuable resource.	
2.4.2 Must be appropriate to the scale of the research project but must not coerce participants to be involved.	

(Links to the National Statement: 2.2.9, 2.2.10, 2.2.11, 4.7.9, 4.7.11)

2.5 Enhancing Aboriginal skills and knowledge

> *Build the capacity of Aboriginal people to participate in and lead research projects. Individuals may be from an Aboriginal Community Organisation, Aboriginal Reference Group, participants or researchers on the project team.* (AH&MRC, 2020, p. 6)

Item	Research content
2.5.1 Ensure that there is a process in place to disseminate information back to the Aboriginal people or communities affected by the research.	
2.5.2 Aboriginal people should be employed on research projects, wherever possible there should be training and development opportunities. There should be an emphasis on employing local Aboriginal people in line with cultural protocols.	
2.5.3 Aboriginal people should be listed investigators on research projects that affect Aboriginal communities. Aboriginal people in the project team should be offered authorship opportunities where possible.	

(Links to the National Statement: 1.1, 2.2.2, 2.2.19, 4.7.7, 4.7.11)

3) Aboriginal Governance

> *There should be structures developed to ensure that appropriate Aboriginal Community engagement is undertaken throughout the entire project from design to final report, not just at the consultation stage. This may be achieved through the oversight of ACCHSs (or appropriate Aboriginal Community*

Controlled Organisation) or an Aboriginal Reference Group. (AH&MRC, 2020, p. 7)

3.1 Direct – ACCHS involvement

Item	Research content
3.1.1 The service has been given the opportunity to determine whether it would like to be a part of the research.	
3.1.2 The service plays an active role in the project and is meaningfully engaged with throughout the project.	
3.1.3 A mutually beneficial agreement has been drafted and consent has been sought from the services.	
3.1.4 Only written support will be considered as evidence. Written support may be in the form of a signed letter of support or a signed organisational consent form, whichever the service may determine appropriate.	
3.1.5 The services have been given all research tools and determine these culturally safe.	
3.1.6 The services have been given the opportunity to review publications prior to dissemination.	
3.1.7 There has been adequate timeframes for the ACCHS to respond appropriately.	
3.1.8 If the project is state-wide, engage with the AH&MRC for a letter of support.	

(Links to the National Statement: 1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10)

3.2 No ACCHS involvement – Aboriginal Reference Group

Item	Research content
3.2.1 Must be representative of the group being studied and have knowledge or experience of the research matter.	

3.2.2 Must be engaged throughout the life cycle of the project not just at the development or consultation stage.	
3.2.3 Develop terms of reference which should include: - Purpose of the group - Membership - Which members identify as Aboriginal - Frequency of meeting - Who will chair the meeting - Who will provide secretariat support - How the group will be reported back to - How will the group be reimbursed for their time.	

(Links to the National Statement: 1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10)

3.3 Aboriginal Researchers:

Item	Research content
3.3.1 Ensure that the research team is adequately staffed with Aboriginal people to assist the cultural navigation of the project	

AH&MRC NSW HREC Submittable application

The details below are in the Submittable form and include the AH&MRC's research principles to meet.

While the AH&MRC require this information to be completed, the AH&MRC checklist at page 10 of its key principes document https://www.ahmrc.org.au/wp-content/uploads/2021/02/9-AHMRC_NSW-Aboriignal-Health-Ethics-Guidelines-Key-Principles-2.pdf states:

"A copy of the Human Research Ethics Application"

If you have a HREA completed that has been approved by or is under review by a different HREC, this can be uploaded to the AH&MRC ethics portal. The HREA is not in lieu of the Submittable form below.

If you are using the AH&MRC as your primary HREC discuss with them how to access the HREA given the AH&MRC do not provide it among their current website materials.

AH&MRC Submittable fields

Title of project

Brief description of the proposed research (275 words)

Name of Chief Investigator

Organisation/Institution

List of researchers/project members on the project, in table online

- ID
- Name of researchers or staff
- Do they identify as Aboriginal and Torres Strait Islander?
- What organisation/institution are they from
- Brief description of their role

Upload a copy of the research/project members CVs

- Limit each CV to 2 pages
- 20 files can be attached

Is the project using statewide data or drawing statewide conclusions?

- If yes, add an AH&MRC letter of support, or a reference group with Aboriginal representation

Aboriginal governance

- ACCHS involved/supportive
- ACCHS led
- Aboriginal Reference Group

NHMRC Field of Research

Proposed stated date

Proposed end data

Is the project a clinical trial?

Does this project have a waiver of consent?

Was there a consultation process with the Aboriginal communities with who the research will take place or the Aboriginal Community Controlled Health Sector?

- If yes, please explain (250 words)

Have you completed a literature review?

- If yes, please explain (250 words)

Have risks been identified, assessed and mitigated?

- If yes, please explain (250 words)

Please demonstrate how this research has implemented Key Principle 1: Net benefits (275 words)

Is this research project co-designed with the Aboriginal Communities affected?

- Will the Aboriginal Community (ACCHS or ARG) have oversight and be engaged with throughout the project from consultation, design, data interpretation to the publication of findings? (explain in 250 words)

Please demonstrate how this research project has implemented Key Principle 2: Aboriginal Community Control of Research (no word limit stated)

- Aboriginal Community Control must be a key focus of all projects affecting Aboriginal people. This means that at all stages of the research project, Aboriginal people and communities participating in or affected by the research will be fully informed about and agree with the purposes and conduct of the project.

Were the communities that are affected by this research project given all the research tools? (explain in 250 words)

- 2.3.5 Questionnaires, surveys, and other documents must be determined culturally appropriate by the Aboriginal people and communities affected.

Please demonstrate how this research project has implemented Key Principle 3: Cultural Sensitivity (250 words)

- Cultural protocols and community decision making processes will vary between Aboriginal communities, researchers should consider this when designing a project. 2.3.1 - 2.3.6

Reimbursement of costs

- Explain how participants are reimbursed for their time and knowledge (250 words)
- Please demonstrate how this research project has implemented Key Principle 4: Reimbursement of costs (also 250 words)

Will you be undertaking capacity building activities with the Aboriginal Researchers on the team?

- Please explain in 250 words

Will Aboriginal people or communities who are involved in the project be acknowledged in publications?

- 2.5.3 Aboriginal people should be listed investigators on research projects that affect Aboriginal communities. Aboriginal people in the project team should be offered authorship opportunities where possible.
- Please explain in 250 words

Supporting documents to upload (up to 50 files)

- research protocol

- letters of support
- appendices.

Do I also have to meet AIATSIS guidelines?

The Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) is federal government funded research organisation with an HREC. Some people working on national research projects often ask *Is just the one clearance from AIATSIS needed?*

Some researchers think that as a Australia's national Aboriginal and Torres Strait Islander research organisation, their HREC can give 'national clearance' for projects.

As at June 2022 this is the *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* available at https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf

However, while the NHMRC do reference AIATSIS and encourage researcher engagement with AIATSIS guidelines, these are not specific to health. AIATSIS has its expertise in humanities, social sciences and cultural studies more generally, rather than health.

There are health-related HRECs to apply to operated by Aboriginal and Torres Strait Islander community controlled organisations in most jurisdictions.

Most of these do not ascribe to the National Mutual Acceptance Scheme – they do not endorse each others' ethics clearances. In my understanding this is to respect the diversity of Aboriginal and Torres Strait Islander cultures and protocols throughout Australia, and rights to self-determine.

For health research, the process is generally:

1. Local HREC clearance e.g., university
2. Aboriginal and Torres Strait Islander community-controlled peak body HREC or committee clearances in relevant jurisdictions e.g., AH&MRC in NSW
3. Other site specific or required clearances.

The following 'ethics companion' website explores research planning and ethics issues for people in the fields of criminology, criminal justice and law: https://www.ethicscompanion.com/

When do I apply for which ethics?

Applications to different HRECs can be made concurrently. However, in my experience and from reviewing over 100 research projects, seek advice from your local HREC to decide.

In my opinion, seek approval from your local HREC first e.g., UTS. This will ensure errors and concerns are addressed locally, with local organisational support and resources, before then applying to the Aboriginal and Torres Strait Islander health

community controlled HREC. This is to reduce the burden on the Aboriginal and Torres Strait Islander community controlled HREC.

If your research is focussed on Aboriginal and Torres Strait Islander people in NSW, you can apply to the AH&MRC HREC first, and only to the AH&MRC HREC. They are a registered HREC providing the same level of clearances as other HRECs. Other committees can be applied to for endorsement under the National Mutual Acceptance Scheme – they can accept, endorse and approve the AH&MRC's cleared project decisions, but not the other way around.

Again, most Aboriginal and Torres Strait Islander community controlled HRECS and other types of research and ethics committees are exempt from the National Mutual Acceptance Scheme.

What other committee clearances might be needed?

Some government departments such as Corrective Services NSW have their own research and/or ethics committees that review research applications. Some details from the CSNSW process are here as an example.

CSNSW has an Application for Approval to Conduct Research form online to be completed, with a length of approximately 12 pages. Most, if not all fields that CSNSW request are covered in the research protocol plan above.

Use the CSNSW 'guidelines' document at:
https://correctiveservices.dcj.nsw.gov.au/csnsw-home/resources/research-and-reports/corrections-research-evaluation-and-statistics/corrective-services-ethics-committee.html

Be sure to check whether site specific approvals are needed e.g., from NSW Health's Local Health Districts. For information about this, and review forms see https://www.medicalresearch.nsw.gov.au/site-authorisation/

For data linkage research, see the Centre for Health Record Linkage https://www.cherel.org.au/

NSW Health has an office of medical research with a website containing grants, new stories, resources on translation and commercialisation, clinical trials and ethics and governance https://www.medicalresearch.nsw.gov.au/

Participation Information Sheet and Consent Form

People who are participating in research have the right to be fully informed about what's involved. And, they have the right to understand in the language/s that are relevant to them.

When developing a participant information sheet, try to think clearly about who your audience is and their literacy levels. There is ample research available which will help guide your decision on this.

The Australian Government recommends that all information for the public be suitable for someone with an age 9 reading level, which is the age of someone in year 3 or year 4 at school. This will ensure that information is accessible to all people.

There are a number of ways to assess the readability of a piece of text, including the Flesch reading ease (for year 9 level: score 100 or more); Flesch-Kincaid grade level (score 4 or below); Gunning FOG (score 4 or below); and SMOG (score 4 or below). Let the HREC know exactly how you have assessed the reading age/s of your audience/s and the content of your Participant Information Sheet (PIS) and Consent Forms.

PIS example

The following Participation Information Sheet and Consent Form (PISCF) template has been designed with permission from forms developed by the AIATSIS and the AH&MRC, and has been used by the Justice Health and Forensic Menal Health Network HREC. It is shared here to guide the design of PISCFs, with an exemplar also at https://www.justicehealth.nsw.gov.au/research/2-piscf-example-3.pdf

The following are elements to include in your PISCF, adding detail about your work and context. Remember to use letterhead, adding version number, date, and contact details. Ensure alignment of all information with the Consent Form, Research Protocol, HREA and other project materials. Seeking feedback on draft/s from diverse stakeholders in your project scope is advised.

Research title: <insert research title>

Researcher(s): <insert name(s) of researcher(s)>

Organisation(s): <insert name>

Research ethics approval number(s):

What is the research about?
This research aims to <describe in plain language what the research project is about>.

Who is doing in the research?
<insert name(s) of researcher(s)>, who work for <insert name of organisation(s)>.

It is paid for by <insert organisation(s)/community group(s) supporting research including details of who is funding the project>.

When and where is the research being done?
It is being done between <insert date(s)> and <insert date(s)> at <insert site(s)>.

Why have you asked me to take part?

We have asked you to take part because
.

Why is the research being done?
We think the research will help <describe the benefits, and who they will go to>.

You can pull out at any time and it won't change how the researcher(s) or anyone else treats you. If you do decide to pull out of the project, please let us know.

If I say yes, what will you do and when?
We will <describe in plain language the research methods and techniques, interview/focus groups/workshop process, use of digital recordings/photographs, etc.>.
The research will happen around the <insert date(s)> at <insert location(s)>.

What do I need to do?
If you agree to take part, you will need to <describe in plain language how much time the participant will need to take part in project>.

What if I change my mind?
If you do agree to take part, then change your mind, you can pull out at any time. It won't change how we or anyone else treats you. If you do decide to pull out, please let us know. We'll ask you to sign a form for our records.

What if I mention something illegal that I have done? (delete if not relevant)
If you tell us about anything illegal you have done, except anything you have already been charged with, we will have to tell the authorities.

And if you tell us about anything that affects the welfare of children, we will have to tell the authorities <could add which>.

What if I get upset by any questions? (delete if not relevant)
You might feel upset by some of the questions we ask. If you don't want to answer a question, you can skip it and go to the next question, or you can stop straight away.

We can arrange for a staff member to talk with you, or tell you about counselling or other support.

Will I be paid?
No. <If the participant will be recompensed in any way, say so here in plain language>.

What will happen to my information?
Your information will be used to create <describe in plain language what the participant's information will be used to create, i.e. report, video, education program, etc.>.

We won't identify you in the report.

You own what you say in our interview.
<Outline who owns copyright of the material being produced>.
<Outline whether reports will be shared with the participant>.

What happens to the results of any tests I do? (delete if not relevant)
We will <describe in plain language whether you will inform the participant and his/her health carer of all results>.

What are the possible risks?
The risks include <describe in plain language any potential risks to the participant and any other risks associated with the research>

We try to reduce these risks by < outline the risk mitigation strategy>

We think the benefit to <describe who gets the benefits> is bigger than the risk to you. But it's up to you to decide.

Storing the information
Anything we learn from you will be stored in <describe in plain language where the data will be stored, i.e. password protected computers/USBs/hard drives, locked filing cabinets, etc.>.

We will store the information for <outline how long the data will be stored for>, then destroy it.

Cultural information (delete if not relevant)
<State whether any culturally sensitive or restricted information will be collected or not, and if so, indicate that permissions will be sought from relevant community organisations, Traditional Owners, Elders, etc.>

Questions or concerns
Do you have any questions? Is there anything you're worried about? If so, please discuss it with us before agreeing to anything.

Contact
Our contact details are <insert name of researcher(s) and contact details>.

Complaints
You can complain about any part of our research to:

- <insert contact details of the researcher(s) supervisor/governing body>
- the Justice Health and Forensic Mental Health Network Human Research Ethics Committee on 02 9700 3443 at
- ethics@justicehealth.nsw.gov.au

If you think there has been a breach of your privacy, you can write to the Office of the Australian Information Commissioner, GPO Box 5218 Sydney NSW 2001 or call 1300 363 992.

Ethics committee approval
The <name HREC> has approved this research. You can contact them on <insert phone number and email> .

Consent form example

Research title: <insert research title>

Researcher(s): <insert name(s) of researcher(s)>

Organisation(s): <insert name>

Research ethics approval number(s): <insert all approvals by organisation and number>

1.	I understand what the research is about	Yes ☐	No ☐
2.	I understand the risks and benefits of being part of this research	Yes ☐	No ☐
3.	I understand what will happen to me during the research	Yes ☐	No ☐
4.	I agree to take part in this research	Yes ☐	No ☐
5.	I know I can pull out of the research at any time and this won't affect any services I receive	Yes ☐	No ☐
6.	I agree that the researcher(s) can interview me	Yes ☐	No ☐
7.	I agree to this interview/focus group/workshop being audio-taped and/or filmed	Yes ☐	No ☐
8.	I agree to photographs being taken of this interview/focus group/workshop	Yes ☐	No ☐
9.	I understand that I <will be/will not be> paid	Yes ☐	No ☐
10.	I agree to having <blood or tissue sample> taken	Yes ☐	No ☐
11.	I know what will happen to my <blood or tissue sample>.	Yes ☐	No ☐
12.	I agree to <insert any other tests or investigations>	Yes ☐	No ☐
13.	I agree that you can see and use my medical records	Yes ☐	No ☐
14.	I understand the results of this research might be published	Yes ☐	No ☐
15.	I agree that my name and other personal information can be mentioned in the <project report/publication that comes from this research>	Yes ☐	No ☐
16.	I understand that all confidential information will be kept safe for <state length of time>	Yes ☐	No ☐
17.	If the researcher(s) keep(s) a record of what I said in a way that could identify me, I give permission for my information to be shared	Yes ☐	No ☐

18. I want the researcher(s) to give me a copy of the <project report/publication> that is produced — Yes ☐ No ☐
19. I know that I own my personal interview recordings — Yes ☐ No ☐
20. I know that if I get distressed or upset during any interview, I can get help from <who, where and how>
21. I understand that the copyright in the <project report/publication> produced as a result of this research will be <shared between / owned by> <insert organisation, community, individual(s)> — Yes ☐ No ☐

Participant to complete:

- I have read the Participant Information Sheet and Consent Form (or someone has read it to me in language I understand) and I agree with it.

Name: _____

Signature: _____ **Date:** / /

Email (to send a copy of this form): _____

Researcher to complete:

- I have described the nature of the research to the participant and I believe that he/she understood and agreed to it.

Name: _____

Signature: _____ **Date:** / /

When can I start?

If certainty is gained that no HREC application for QI or QA is required, activities can commence, after adhering to any other institutional requirements.

HREC approval cannot be applied for or provided after QI and QA activities have begun, or retrospectively.

Applications to HRECs need to receive written approval from all sources before research can begin.

Some researchers state in their HREA 'the research will begin when ethics clearance is obtained'. While this might be the case, it is impossible for an HREC to ascertain all the steps and contingencies for a research project and their timeframe within their resources. So, do provide a timeframe. Provide an estimated start time based on when you think you might gain HREC approval to commence your research.

An example of a timeline is below.

Timeframe template

Example of basic project schedule identifying timing of various project stages.

	March				April				May				June			
1. Scoping, engagement and development																
2. Consult and Codesign																
3. Ethics review																
4. Data collection																
5. Feedback																
6. Documentation																
Collaboration meeting schedule																
Core design team																
Organisational reference																
External reference group																
Elder reference group																

Research translation

According to the range of ethical research guidelines above, ‘research translation’ should never be designed to occur at the end of a project.

See this suite of material for ideas about knowledge exchange from Aboriginal and Torres Strait Islander people’s perspectives: https://www.lowitja.org.au/page/services/resources/health-policy-and-systems/knowledge-translation/profiling-excellence---indigenous-knowledge-translation

At the very least, have a research output plan. Here is one example: https://www.lowitja.org.au/page/services/resources/health-policy-and-systems/knowledge-translation/profiling-excellence---indigenous-knowledge-translation

Research output planning template

Ensure agreement among all research team members about what will be conveyed about the project, when and how. Create the following or similar, keep it as a living

document, and reflect on it regularly e.g., as a standing item in research team meetings.

Title	Audience/place	Authors	Data	Argument/ narrative	Timeframe	Contingencies

Budget template

Ethical research requires resources, and ethics applications need to establish how the research can feasibly be conducted with the resources at hand.

Use a clear template such as the below to list all budgeted costs; in-kind contributions with actual funds can also be included here with a dollar figure to show more accurate contributions to projects and stakeholders.

This is a very basic table with quite plain text in Word to avoid complications with other project and budget apps, plug-ins or spreadsheets. Given ethics application require many peoples' input and checking, keep file-shareability very manageable.

Item	Amount	Rate	Cost (excl. GST)	GST	Cost (incl. GST)
Name	xxx days	$xxxx			
Name	xxx days	$xxxx			
Name	xxx days	$xxxx			
Community consultations	4 communities	$xxxx			
Travel and accommodation	4 communities	$xxxx			
Design and artwork	1 report	$xxxx			
Transcripts					
Aboriginal Advisory Group					
Aboriginal Data Sovereignty Group					
Other expertise					

TOTAL

Milestone payment template

Milestone payments are required to receive research project funds. They can be a useful way to reiterate project phases to a research team and stakeholders and to HRECs, beyond their importance with funding bodies. Milestones require clear thinking about project phases and how research integrity is built, including through use of resources.

One example is:

Date	Milestone	Payment (excl. GST)	GST	Payment incl. GST
June 2022	Project plan and evidence of initial community engagement			
December 2022	Ethics clearance			
June 2023	Midway report			
December 2023	Satisfactory progress			
June 2024	Data analysis			
December 2024	Satisfactory progress			
June 2025	Final report			
TOTAL				

Does the research need an amendment?

Researchers considering seeking an amendment to ethics approval should ask themselves the following questions about the changes they wish to make to their research.

- Does the change significantly increase or decrease the number of participants?
- Does the change alter the approved methodology?
- Does the change make any difference to the research question/s approved?
- Does the change increase any risk, or decrease any benefit, to participants?
- Does the change add or remove any group considered in section 4 of the National Statement? That means women who are pregnant and the human fetus; children and young people; people in dependent or unequal relationships; people highly dependent on medical care who may be unable to give consent; people with a cognitive impairment, an intellectual disability or a mental illness; people who may be involved in illegal activities; Aboriginal and Torres Strait Islander peoples; or people in other countries.

- Does the change introduce a new conflict of interest, or exacerbate an existing one?
- Does the change alter the approved need for or approach to consent?

If you can answer ‘no’ to all questions above, the changes to your research project should be submitted as an amendment for review and approval. If the answer is ‘yes’ to any question, then a new application is likely to be needed, submitted online.

Changes to the original research protocol or research plan need to be clearly identified. Accurate, consistent detail is required in the amendment form as in the updated research protocol.

References

Aboriginal Health and Medical Research Council of NSW. (2020). *NSW Aboriginal health ethics guidelines: Key Principles*. Sydney: AH&MRC. https://www.ahmrc.org.au/wp-content/uploads/2021/02/9-AHMRC_NSW-Aboriignal-Health-Ethics-Guidelines-Key-Principles-2.pdf

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National Health and Medical Research Council (NHMRC). (2018a). *National Statement on ethical conduct in human research.* Canberra: Australian Government. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

NHMRC. (2018b). *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*. Canberra: Australian Government. https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples

NSW Government. (2007). *NSW Health’s quality Improvement & ethical review: A practice guide for NSW.* Sydney: NSW Government. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2007_020.pdf

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