

## AH&MRC Ethics Committee Position on Risk and Review Requirements

### Overview

The AH&MRC Ethics Committee does **not** consider any research involving Aboriginal and Torres Strait Islander Peoples to be *low risk* and does **not** accept Low Risk Human Research Ethics Applications (HREAs). All such research must be submitted for **full ethics review**.

This position is based on long-standing ethical concerns, historical and ongoing harm caused by unethical research, and a collective understanding of risk that considers both individual and community-level implications. While researchers may assess a project as low or negligible risk to individuals, this does not reflect the lived experience or cultural safety expectations of Aboriginal and Torres Strait Islander Peoples as collective, sovereign Peoples.

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### Changes to the National Statement (2023–2025): Risk Assessment and Review

The 2023 revisions to the *National Statement on Ethical Conduct in Human Research* replaced the previous fixed categories of “negligible,” “low,” and “greater than low” risk with a **risk continuum model**. Risk is now assessed on a **spectrum**, and the level of ethical review is expected to be **proportional** to the level of risk.

However, the AH&MRC Ethics Committee affirms that:

- **All research involving Aboriginal and Torres Strait Islander Peoples must undergo full HREA review, regardless of perceived risk.**
- **No projects involving Aboriginal and Torres Strait Islander participants or communities will be considered low risk or eligible for exemption.**

This position is upheld even in the context of:

- Limited disclosure or deception (National Statement 2.3.1.c and 2.3.6.a),
- Waiver of consent (2.3.10.a),
- Genomic research (p.48), and
- Research that may be eligible for exemption from review (5.1.17 a-d).

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### Clarification on “Negligible” and “Low” Risk Research

The *National Statement* describes “negligible risk” as involving only inconvenience, and “low risk” as involving foreseeable discomfort but no serious harm. However, this framing **does not align** with Aboriginal and Torres Strait Islander worldviews and research experience.

Projects that may seem individually low risk may still:

- Cause harm through a lack of cultural safety,
- Overlook collective or reputational risks to communities and Peoples,
- Disregard proper consultation, governance, and data sovereignty principles.

Importantly, the term “Peoples” is used to recognise Aboriginal and Torres Strait Islander Peoples as **political and cultural collectives**, not just individuals. Researchers must distinguish between **individual risk** and **collective risk**—a nuance that is critical in First Nations research contexts.

#### **Ethical Review Pathways and Governance (Section 5 – National Statement)**

- **5.1.10–5.1.13** outline that proportional review pathways must match the level and type of risk. However, risks to Aboriginal and Torres Strait Islander Peoples cannot be fully captured in standard individualised risk models.
- **5.1.16** clarifies that use of personal information without consent requires a waiver by an appropriate HREC and **cannot be exempt from review**.
- **5.1.17 a–d** sets out limited conditions under which exemption from ethics review may be granted—**none of which apply where Aboriginal and Torres Strait Islander Peoples are involved**.

#### **Research Exemptions – Not Applicable to Aboriginal and Torres Strait Islander Research**

Although the National Statement allows institutions to consider exemption from ethics review in limited cases (Section 5.1.17), the AH&MRC does not apply these exemptions to any research involving Aboriginal and Torres Strait Islander Peoples.

**Circumstances listed in the National Statement that may be considered for exemption by institutions include:**

- Use of de-identified data with no attempt to re-identify individuals;
- Surveys or public observation with no personal identifiers;
- Research as part of internal education/training not for external publication;
- Use of publicly available data protected by law;
- Internal audits or quality assurance activities that do not extend beyond standard practice.

**However, the following apply:**

- **Any research involving Aboriginal and Torres Strait Islander Peoples within NSW is not eligible for exemption.**
- **Any use of personal information without consent requires ethics review and cannot be exempted.**

#### **Submission Requirements for Research Involving Aboriginal and Torres Strait Islander Peoples**

Any health and wellbeing research involving Aboriginal and Torres Strait Islander people within NSW must be submitted as a full Human Research Ethics Application ( HREA) to the AH&MRC Ethics Committee. This ensures review of:

- **Cultural safety** for individuals and communities,
- **Genuine community engagement** and appropriate governance,

- **Sensitivity to the political, historical, and social context** of research involving Aboriginal and Torres Strait Islander Peoples,
- **Respect for data sovereignty and Indigenous knowledges.**

#### Summary: AH&MRC Review Requirements

Research Type	Accepted by AH&MRC Ethics Committee?	Required Review Pathway
Low-risk HREA	<input checked="" type="checkbox"/> Not accepted	Full HREA required
Research involving Aboriginal or Torres Strait Islander Peoples	<input checked="" type="checkbox"/> Yes	Full HREA required
Research requesting waiver or limited disclosure	<input checked="" type="checkbox"/> Case-by-case	Full HREA required
Genomic research	<input checked="" type="checkbox"/> Yes	Full HREA required
Research seeking exemption under 5.1.17 (a-d)	<input checked="" type="checkbox"/> Not eligible if involving Aboriginal or Torres Strait Islander Peoples	Full HREA required