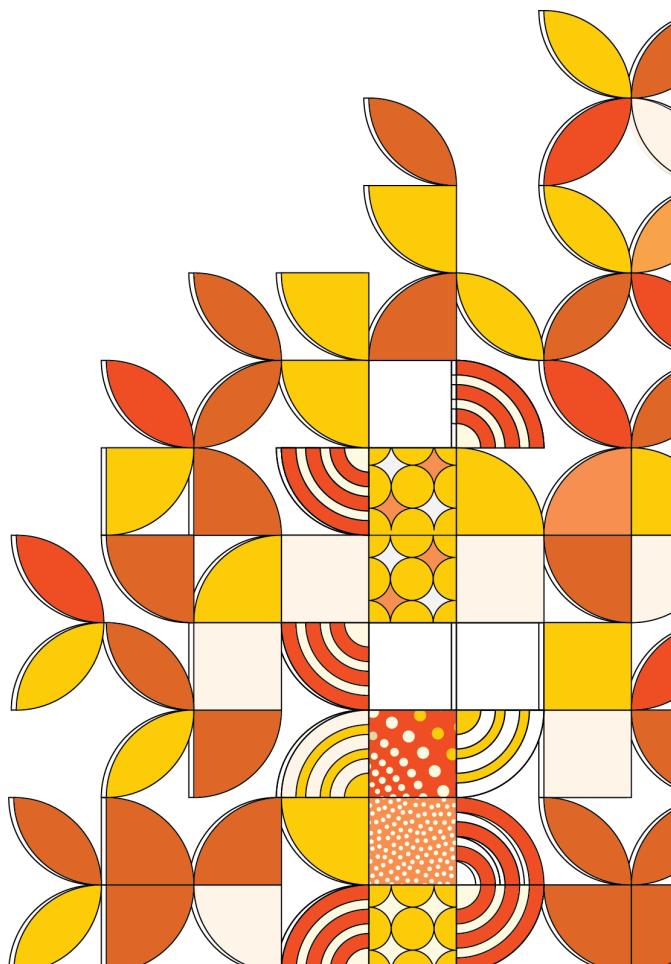


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CONCEPT NOTE

Ethics review pathway for lower risk research under the National Statement 2025

Proposal for IHM Low-Risk Human Research Ethics Panel (LR-HREP)

Introduction

IHM attempted to establish a standalone HREC. The Academic Board recommended that IHM better partner with any other university/institute to share the third-party HREC. IHM assessed the possibility of this collaboration with Victoria University, Charles Darwin University and a research institute. While the universities are unwilling to lend their HRECs to IHM, the external organisation's charges for ethics review are quite prohibitive. In this context, IHM now proposes to establish a non-HREC pathway to review lower or negligible risk research at IHM.

This proposal is based on the rules laid down in the *National Statement on Ethical Conduct in Human Research 2025* (National Statement 2025), which will come into force on 1 October 2025.¹

Per 5.1.12 of the National Statement 2025, IHM can establish pathways for review of lower-risk research. The purpose should be to enable efficient and proportionate review of lower-risk research.

Proposal: That a Low-Risk Human Research Ethics Panel (LR-HREP) be established under the direct supervision of the Academic Board.

Rationale: To encourage low-risk research as well as capstone units research, interviews, or surveys by students, in particular, work that may potentially mature into research publications.

Benchmarking: There can be 3 models of non-HREC pathway bodies: (a) review by a designated committee or person(s) within an institution; (b) review by a sub-committee or the Chair/Deputy Chair of an HREC; and (c) review at departmental level by the head of department or a committee of peers. Some universities have non-HREC pathways as part of HREC (e.g., CDU), and some universities have faculty-based lower-risk ethics panels (e.g., University of Queensland).

Inspired by the University of Queensland model, IHM proposes to establish a single Panel for both social work and nursing research.

Requirements and what to be done

Higher risk research must be reviewed by HREC. Research involving no more than low risk (**lower risk research**) may be reviewed under other processes such as the LR-HREP proposed at IHM. IHM may also determine that some human research is exempt from ethics review (5.1.15 to 5.1.18 National Statement 2025).

lower risk research can be classified to “minimal” risk and “**low**” risk research. Low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort. Research in which the risk for participants or others is greater than discomfort (**risk of harm involved**) is not low risk research.

IHM has developed a guideline to define, by risk profiling, low risk, negligible/minimal risk, and high-risk research. This guideline sets criteria based on which a research proposal (such as capstone units research or interviews or surveys by students) can be classified as low risk research.

¹ At that point, the 2023 National Statement (in force since January 2024) will be replaced.

Requirements for the ethics review of lower risk research and the criteria for granting an exemption from ethics review are set out in Chapter 5.1.13 to 5.1.18 of the National Statement 2025. These rules (in the context of IHM) are summarised as follows:

- **Regular Assessment of Review Processes:** IHM should regularly evaluate its ethical review process and the criteria for low-risk research, ensuring alignment with the National Statement (5.1.13).
- **Incorporating Participant and Community Feedback:** Ethics reviews should be informed by participant experiences or community involvement (5.1.14).
- **Addressing Emerging Ethical Issues:** IHM must stay alert to emerging ethical concerns that may require adjusting the review level (5.1.15).
- **Transparency Through Reporting:** IHM should produce and share regular reports on ethical review processes to support evaluation (5.1.16).
- **Auditing Review Allocations and Exemptions:** An audit system should confirm correct review levels and exemptions granted under Ch 5.1.22–5.1.23 (5.1.17).
- **Resources and Capacity for Non-HREC Reviews:** IHM must ensure its LR-HREP is properly resourced and professionally staffed (5.1.18).

Any non-HREC pathway should also adhere to [Australian Code for the Responsible Conduct of Research \(2018\)](#), [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities \(2018\)](#), and TEQSA [Guidance note: Research and research training](#).

To implement the proposal, several documents need to be developed, an Office of Research needs to be established to which the Research and Innovation Manager should be attached, and a portal needs to be created on the IHM website. These can be summed as:

- Create an Office of Research.
- Appoint Research and Innovation Manager or any other officer as Research Integrity Officer.
- Create a research portal (e.g., [MyResearch@IHM](#)).
- Create an email address box, such as reserchethics@ihm.edu.au.
- Finalise the draft Research, Scholarship, and Publications Framework ([completed, to be presented to the Academic Board](#)).
- Develop TORs of LR-HREP as per rules in Chapter 5.1.13 to 5.1.18 of the National Statement ([completed, to be presented to the Academic Board](#)).
- Develop a Guideline on Low and Negligible Risk Research ([completed, to be presented to the Academic Board](#)).
- Develop a Low-Risk Human Research Ethics Procedure ([completed, to be presented to the Academic Board](#)).
- Develop an *Application Form for Low-Risk Research Ethics Approval* ([completed, to be presented to the Academic Board](#)).
- Develop a *Low-Risk Research Ethics Approval Form* ([completed, to be presented to the Academic Board](#)).
- Develop other necessary forms such as the *Application Form for Low-Risk Research Ethics Approval* and *Low-Risk Research Ethics Approval Form* ([completed](#)).
- Complete the risk assessment (an Explanatory Note on risks identified and mitigation plan (for IHM governance purposes) ([completed, to be presented to the Academic Board](#)).

Governance

To get the full approval of governance bodies, it is proposed:

- A meeting among Board Chair, CEO, Academic Board Chair, Director, Quality Management and GRC rep (as soon as practicable).
- Presenting the proposal and all documents to Learning and Teaching Committee.
- Presenting to Academic Board for approval.
- Presenting to Board of Directors for endorsement.

Attachments:

1. Risk Assessment (internal) for the LR-HREP.
2. All documents (including policies) required.