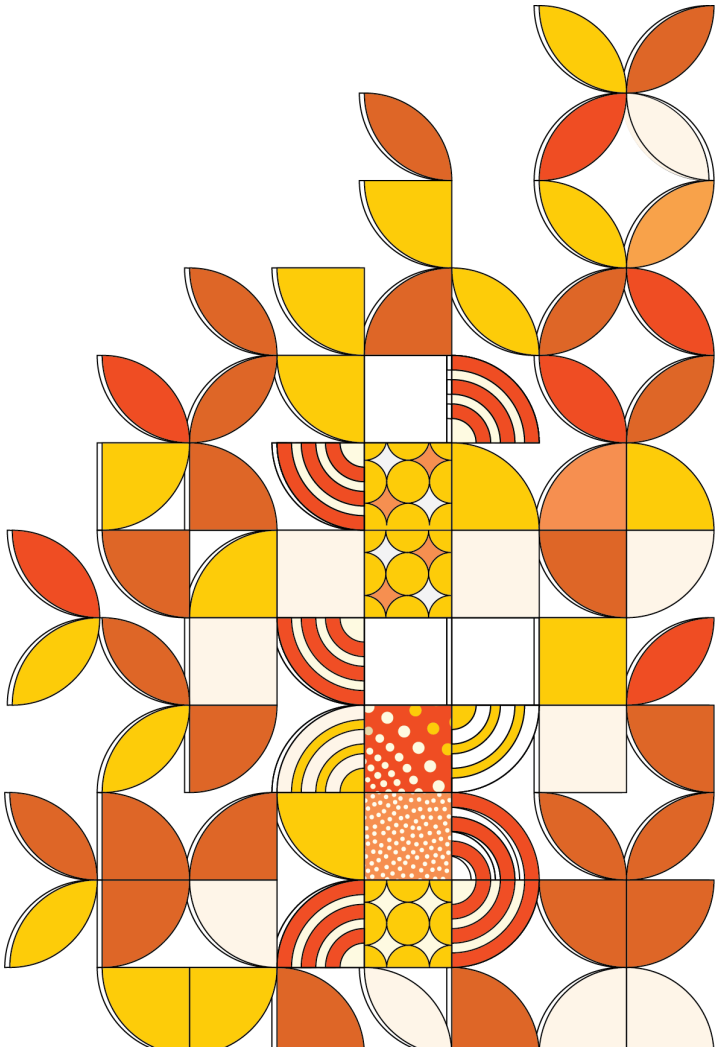
Legal entity: INSTITUTE OF HEALTH & MANAGEMENT PTY LTD.
Category: Institute of Higher Education
CRICOS Provider: 03407G| Provider ID: PRV14040
ABN: 19 155 760 437 | ACN: 155 760 437

Low-Risk Human Research Ethics Procedure



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SECTION 1

Purpose

1. This procedure outlines the ethical review and approval process for low and negligible-risk human research conducted at the Institute of Health and Management (IHM). It adheres to the National Statement on Ethical Conduct in Human Research (2025), the Australian Code for the Responsible Conduct of Research (2018), and relevant guidelines issued by:
   1.1 National Health and Medical Research Council (NHMRC).
   1.2 Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS).
   1.3 Tertiary Education Quality and Standards Agency (TEQSA).
   1.4 Office of the Australian Information Commissioner (OAIC).
2. Ethical approval must be obtained prior to research commencement. Approval ensures the rights, safety, and welfare of research participants are protected and risks are minimised.

Scope

3. This procedure applies to any low or negligible risk human research undertaken at IHM.
4. This Procedure applies to all IHM staff and students undertaking research (low risk) and to all external researchers planning to conduct research in collaboration with IHM.

Definitions

5. For the purposes of this Procedure:
   5.1 Low-Risk Research is human research where the only foreseeable risk is discomfort (physical, psychological, social, or cultural). Discomfort may include minor side effects or mild anxiety (e.g. routine blood pressure measurement or a brief survey) but not harm.
   5.2 Negligible-Risk Research is research where there is no foreseeable risk of harm or discomfort apart from minor/negligible inconveniences to research participants. This category requires only the simplest oversight since participants are not expected to experience anything beyond a trivial bother.
6. For definitions of other terms used in this Procedure, refer to IHM's Glossary of Terms.

Suite documents

7. This Procedure is linked to the following suite documents:
   7.1 Guideline on Low and Negligible Risk Research.
   7.2 See also the Associated Information listed in the 'Related Internal Documents' in Section 3 below.

SECTION 2

Low-Risk Human Research Review

8. The IHM Low-Risk Human Research Ethics Panel will review low-risk research ethics approval

applications. Refer to the IHM Low-Risk Human Research Ethics Panel (LR-HREP) Terms of Reference for detailed information.

9. Researchers must design research in line with ethical principles, submit complete applications, manage risks, and ensure proper consent (i.e., excluding research containing secondary datasets).
10. The IHM Office of Research oversees the submission of eligible low-risk research proposals and maintains appropriate records of all applications and approvals. It provides guidance (e.g. templates for information sheets/consent) and forwards eligible proposals to the Low-Risk Human Research Ethics Panel.

Risk Categorisation and Review Pathways

11. All human research proposals must be assessed and categorised by the level of risk prior to ethical review, in accordance with the National Statement 2025.
    - 11.1 Low-risk research, merely involving foreseeable discomfort, is reviewed by the Low-Risk Human Research Ethics Panel (LR-HREP).
    - 11.2 Research such as negligible risk research may be eligible for exemption from formal ethics review if it meets all criteria under Clause 5.1.17 of the National Statement. Researchers must formally apply for exemption, and approved exemptions are documented by the Office of Research (see clause 24).
    - 11.3 Any proposal involving more than low risk, or vulnerable populations (such as children, people with cognitive impairment, or members of Indigenous communities without appropriate safeguards), is excluded from this procedure and is not eligible for low-risk review.

Low-Risk Human Research Review Process

12. Application Submission: Researchers submit the Low-Risk Ethics Application available application form on the IHM website or through the portal, including but not limited to project summary, methodology, risk assessment, participant information sheet, consent form (if required), and data management plan.
13. Submissions must address ethical principles (respect, beneficence, justice) and participant welfare.
14. Screening: IHM Office of Research verifies eligibility under low-risk criteria in accordance with the National Statement and IHM Guideline on Low and Negligible Risk Research.
15. Projects involving Indigenous participants, sensitive data, or health information are flagged for further review or privacy compliance.
16. Panel Review: Eligible applications are reviewed by the Low-Risk Human Research Ethics Panel (LR-HREP) via face-to-face or online. The panel evaluates:
    - 16.1 Risk level and mitigation.
    - 16.2 Consent process and documentation.
    - 16.3 Collected data and information management.
    - 16.4 Compliance with cultural and privacy standards.

16.5 Justification of potential risks vs benefits.

16.6 The panel may seek clarifications or refer projects exceeding low risk to the full HREC.

Decisions

17. The panel issues its decision in writing.
18. The possible outcomes are:
    18.1 Approved.
    18.2 Approved with conditions.
    18.3 Resubmit with changes
    18.4 Rejected.
19. Records of the decision and any minutes are maintained by the IHM Office of Research.
20. IHM will maintain a fast review process with a turnaround time typically of 4 to 6 weeks to facilitate timely research.

Post-Approval Monitoring and Reporting

21. Researchers must follow the approved protocol, submit amendments for review, and provide progress/final reports.
22. IHM Office of Research/Officer will conduct periodic audits to ensure compliance with ethical standards, institutional policies, and approval conditions for all approved low-risk research projects..
23. Any adverse events or ethical issues arising during the research must be reported immediately.

Exemptions from Ethics Approval

24. IHM may exempt certain low-risk Human research projects from review if they meet National Statement requirements under chapter 5.1.17. Examples include, but are not limited to:
    24.1 De-identified Data: Use of existing records or specimens with all personal identifiers removed and strong assurances against re-identification.
    24.2 Public Observation: Surveys or observation of public behaviour where data are non-identifiable and no distress is likely.
    24.3 Student Projects: Research carried out solely for training/education for internal use only (no publication intent) with only minimal risk.
    24.4 Public Information: Analysis of information publicly available under law (e.g. statistics, register data).
25. Researchers must apply for exemption; changes increasing risk require full ethics review.

Special Considerations for Indigenous Research

26. Any low-risk research involving Aboriginal and Torres Strait Islander Peoples must:
    26.1 Demonstrate meaningful engagement and partnership with Indigenous communities.
    26.2 Ensure cultural protocols and values are respected.

26.3 Provide tangible benefits to the participating communities.

26.4 Adhere to the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research 2020.

26.5 Adhere to the NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders August 2018

Privacy and Data Management

27. Research involving identifiable or sensitive data must follow Privacy Act Guidelines (Sections 95/95A).
28. Applications must include appropriate data management plans and privacy justifications.
29. Personal and health information must be handled with strict confidentiality and security.
30. Data should be stored securely, with access limited to only the authorised personnel (i.e., Data is stored on password-protected IHM servers or approved cloud storage platforms (e.g., OneDrive, SharePoint, or institution-provided research drives).

Academic and Research Integrity

31. Researchers must uphold principles of honesty, rigour, and transparency.
32. All research activities should align with TEQSA's guidance on academic and research integrity.
33. Any breaches of integrity must be reported and addressed promptly in accordance with the IHM Academic Honesty and Integrity Policy and Procedure.

SECTION 3

Associated Information

Related Internal Documents	• Research, Scholarship, and Publication Framework • Low-Risk Human Research Ethics Panel (LR-HREP) Terms of Reference • Guideline on Low and Negligible Risk Research • Low-Risk Human Research Ethics Procedure • Application Form for Ethics Approval for Low-Risk Human Research • Participant Information Sheet (PIS) Template • Low-Risk Human Research Consent Form Template • Approval Form for Low-Risk Human Research • Decision Letter Template • Progress/Completion Report Form • Academic Honesty and Integrity Policy and Procedure • Risk Management Policy and Procedure • Risk Management Framework • Student Code of Conduct • Student Code of Conduct Implementation Guidelines • Staff Code of Conduct • Complaints and Appeals Policy and Procedure • Staff Complaints and Grievances Procedure • Bullying and Harassment Prevention Policy and Procedure • Sexual Assault and Sexual Harassment Prevention and Response Policy

	and Procedure • Fraud and Corruption Prevention and Control Policy • Whistleblower (Fraud and Corruption Prevention and Control) Procedure
Related Legislation, Standards, and Codes	• Tertiary Education and Quality Standards Agency Act 2011 • Higher Education Standards Framework (Threshold Standards) 2021 Domain 4 (Research and Research Training) Domain 6 (Governance and Accountability) • TEQSA Guidance note: Academic and research integrity 2024 • TEQSA Guidance note: Research and research training 2024 • National Statement on Ethical Conduct in Human Research 2025 • Australian Code for the Responsible Conduct of Research 2018 • NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders August 2018 • NHMRC Ethical considerations in quality assurance and evaluation activities 2014 • NHMRC Guidelines Under Section 95 of the Privacy Act 1988 • NHMRC Guidelines Under Section 95A of the Privacy Act 1988 • Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research 2020 • Privacy Act 1988 (Cth) • State and territory privacy laws • Any other relevant Commonwealth, State, or Territory legislation or guidance
Date Approved	
Date of Effect	
Date of Next Review	
Approval Authority	Academic Board (endorsed by the Board of Directors)
Responsibility for implementation	Low-Risk Human Research Ethics Panel and Academic Dean
Document Custodian	Research and Innovation Manager
IHM Doc ID	IHM-LR-HREP2-1.0

Change History

Version Control		**Version 1.0**
Change Summary	**Date**	**Amendment Details (brief description)**
Version 1.0	10/06/2025	New Low-Risk Human Research Ethics Procedure