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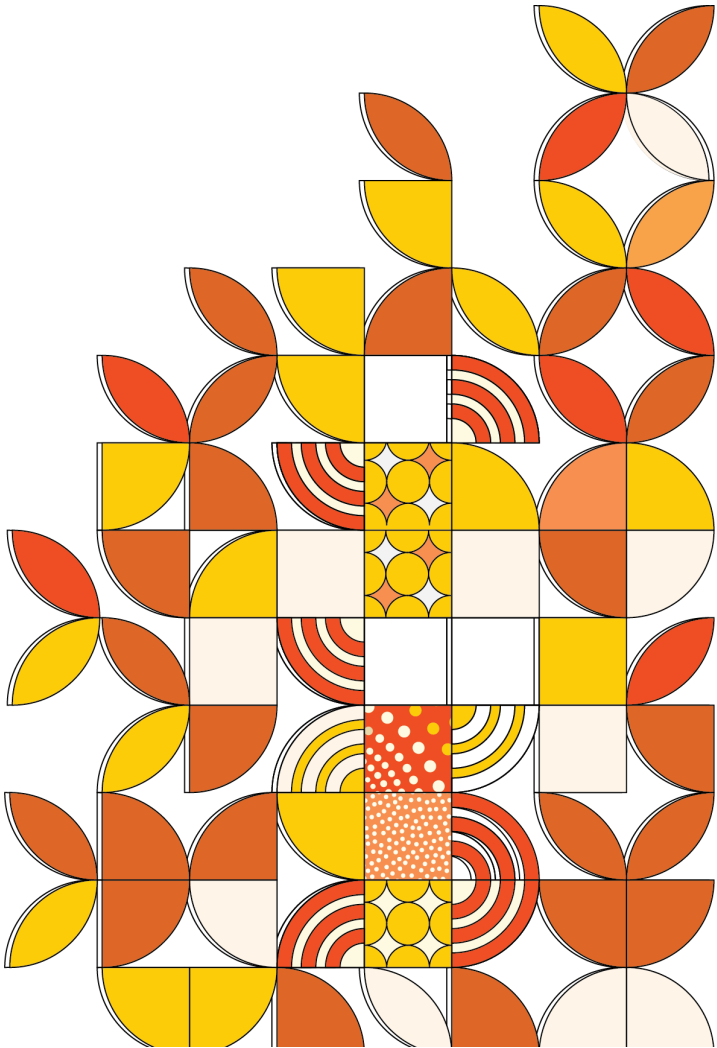
Guideline on Low-Risk Research



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EDUCATION *for* EMPLOYMENT:
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SECTION 1

Purpose

1. This Guideline outlines principles based on which a research project at the Institute of Health and Management (IHM) can be profiled as low-risk research.
2. This Guideline is intended to provide IHM's Low-Risk Human Research Ethics Panel (LR-HREP) with a tool for reviewing and evaluating any low or negligible risk research project based on principles and requirements of the National Statement on Ethical Conduct in Human Research 2025 (National Statement).
3. This Guideline is intended to aid the researchers in understanding and applying low-risk research concepts contained in the National Statement when developing, conducting, and managing their research.

Scope

4. This Guideline applies to all human research activities conducted within IHM that are of low or negligible/minimal risk to research participants.
5. It does not apply to any animal research.
6. It does not apply to a human research project that can be profiled as higher-risk research, where risk is greater than low or high.

Definitions

7. For the purposes of this Guideline,
   - 7.1 **Discomfort** is considered less serious than harm. It can involve **mild anxiety** associated with an interview or **minor physical or psychological impacts** as, for example, minor side effects of medication, or discomfort related to non-invasive tests such as measuring blood pressure.
   - 7.2 **Higher risk research** is research that involves more than low risk, that is, harm to research participants or human beings generally. Research of this profile must be reviewed by an HREC in accordance with the National Statement.
   - 7.3 **HREC** is the Human Research Ethics Committee that may be established by any organisation in accordance with the National Statement.
   - 7.4 **Human research** refers to research conducted with or about people, or their data or tissue, as described in the National Statement on Ethical Conduct in Human Research 2025.
   - 7.5 **Low-risk research** is 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.
   - 7.6 **Research** can be defined as an original investigation undertaken to gain knowledge, understanding and insight as described in the Australian Code for the Responsible Conduct of Research 2018 (Australian Code).
   - 7.7 **Negligible or minimal risk research** is research where there is no foreseeable risk of harm or discomfort,

and any foreseeable risk is not more than an inconvenience to the participants.

Suite Documents

8. This Guideline should be read in conjunction with the following IHM documents and external instruments:
   8.1 Low-Risk Human Research Ethics Procedure
   8.2 Low-Risk Human Research Ethics Panel (LR-HREP) Terms of Reference
   8.3 See also the Associated Information listed in the 'Related Internal Documents' in Section 3 below.

Legal and Legislative Framework

9. This Guideline should be read in conjunction with the following legal and legislative documents:
   9.1 National Statement on Ethical Conduct in Human Research 2025 (National Statement).
   9.2 Australian Code for the Responsible Conduct of Research 2018.
   9.3 NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders August 2018.
   9.4 Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research 2020.
   9.5 Privacy Act 1988 (Cth).
   9.6 Any other relevant Commonwealth, state, or territory legislation or guidance.

Determination of Level of Risk and Appropriate Level of Review

Risk

10. Risk refers to the possibility of causing harm, discomfort, or inconvenience. It involves both the potential that such effects might occur and the seriousness of their impact.
11. Risks can be physical, psychological, emotional, spiritual, legal, or social in nature. While no list of harms can be exhaustive, the following types of potential harms in or from research should be noted:
12. *physical* harm: including injury, illness, pain or death.
13. *psychological harm*: including feelings of worthlessness, distress, guilt, anger, fear or anxiety related to disclosure of sensitive information, for example.
14. *devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly.*
15. *cultural harm: including misunderstanding, misrepresenting or misappropriating cultural beliefs, customs or practices.*
16. *social harm*: including damage to social networks or *relationships* with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and unauthorised disclosure of personal information.
17. *economic harm*: including the imposition of direct or indirect costs on participants.

18. *legal harm*: including discovery and prosecution of criminal conduct.
19. These risks may affect not only participants but also others, such as family members or broader social groups.
20. Harm and discomfort to non-participants may also be relevant to the assessment of the risks of a research project. Examples of risks to non-participants from research include the risk of distress for a participant's family member identified as having a serious genetic disorder, the possible impact of information in published research on family or friends, or the risks of biological research to the community.
21. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values or business investment.
22. Research into the impact of public health policy on community wellbeing or into social determinants of health may also carry a risk of harm to participants or their communities.
23. The level of risk may change depending on circumstances. However, where a person's reactions might exceed discomfort and mature into distress, this should be viewed as a potential for harm, with the implication that the research risk is greater than low.

Risk profiles

24. Research can be profiled into four categories: a) negligible/minimal risk, b) low risk, c) greater than low risk, and d) high risk.
25. Low and negligible risk research can together be called lower risk, while greater than low risk and high risk research can together be called higher risk research.

Table 1: Risk Profiles of Research

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Negligible (minimal)	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

* Burden & inconvenience outlined in Section 2.1 of the National Statement 2025

Review of Low and Negligible/Minimal Risk Research Ethics

26. Research posing negligible risk, in accordance with Clause 5.1.17 of the National Statement 2025, may be exempt or conditionally approved by the IHM Low-Risk Human Research Ethics Panel (LR-HREP), in line with this Guideline and the IHM Low-Risk Human Research Ethics Procedure.

27. Researchers must obtain prior approval from the Low-Risk Human Research Ethics Panel (LR-HREP) before commencing any research classified as low-risk.
28. The higher risk research as defined in clause 7 above cannot be approved by the IHM Low-Risk Human Research Ethics Panel (LR-HREP). For such research projects, IHM researchers may collaborate with external researchers whose organisations have established any HREC.

Research Projects Suitable for LR-HREP Ethics Review

29. The following types of research may be suitable for review by LR-HREP if the research involves no more than low risk:

29.1 Data Collection and Use:

a) Anonymous or non-identifiable surveys with non-sensitive questions.
b) Online questionnaires where participants are recruited via public or generic links (e.g., social media).
c) Focus groups or interviews that avoid highly sensitive topics and where accidental disclosure won't cause serious harm.
d) Creation or use of data registries using non-identifiable data from existing datasets for the use of which permission of the data owner is not required.

29.2 Use of Existing Bio-Specimens

a) Existing specimens collected under broad or unspecified consent.
b) No risks to donors or communities beyond minor discomfort.
c) Specimens must be non-identifiable to researchers.
d) The research should not generate health-related findings for individuals or families.

29.3 Minimal or Non-Invasive Procedures

a) Activities like reading, watching videos, playing online games, solving puzzles, or performing simple cognitive tasks.
b) No physical or medical interventions.

29.4 Desk-based review or report, or literature review, or a research paper (qualitative analyses) involving no personal information and without a breach of copyright/intellectual property laws.

Research Projects Beyond LR-HREP's Scope of Responsibility

30. The following categories of research are **not eligible** for review by the IHM Low-Risk HREP, regardless of the assessed risk level, which must be reviewed by a Human Research Ethics Committee (HREC) established under the National Statement.

30.1 Waiver of Consent: Research seeking to waive participant consent (e.g., use of identifiable health information without consent) requires HREC approval. LR-HREP cannot grant waivers (NS 2.3.9–2.3.11).

30.2 Use of Unconsented Biospecimens: Projects involving human biospecimens without specific or consistent consent, or outside the original consent scope, require HREC review (NS 3.2.14).

30.3 Genomic Research: All genomic research, including projects proposing a waiver of consent, must be reviewed by a full HREC (NS 3.3; NS 3.3.14).

30.4 Sharing of Genomic Data: Genomic data sharing beyond the original consent scope requires HREC review and approved transfer agreements (NS 3.3.24(b)).

30.5 Derivation from Human Embryos: Research involving the derivation of embryonic stem cell lines or products from human embryos must undergo full HREC review (NS 3.2.1).

30.6 Prospective Collection or Biobanking: Establishing biobanks or collecting new human biospecimens for research requires HREC-approved protocols (NS 3.2.1–3.2.2).

30.7 Exportation of Biospecimens: Exporting human biospecimens must align with the original consent and be approved by an HREC (NS 3.2.9(b)).

30.8 Biospecimens Yielding Significant Health Findings: Research using biospecimens that may reveal important health-related information must have a management plan approved by an HREC (NS 3.2.15).

30.9 Xenotransplantation: All research involving animal-to-human xenotransplantation must be reviewed by an HREC (NS 3.4).

30.10 Research Involving Vulnerable Populations or Sensitive Contexts: The following participant groups and contexts require full HREC review:

a) Pregnant women and fetuses, including fetal tissue (NS 4.2).

b) People highly dependent on medical care, such as hospitalised or involuntary patients (NS 4.4)

c) Individuals with cognitive impairment, intellectual disability, or mental illness requiring enhanced safeguards (NS 4.5).

d) Research likely to expose or uncover illegal activity unless fully de-identified data is used (NS 4.9).

e) Aboriginal and Torres Strait Islander Peoples requiring culturally appropriate engagement and HREC oversight (NS 4.7).

Research Projects that may be Exempted from Ethics Review

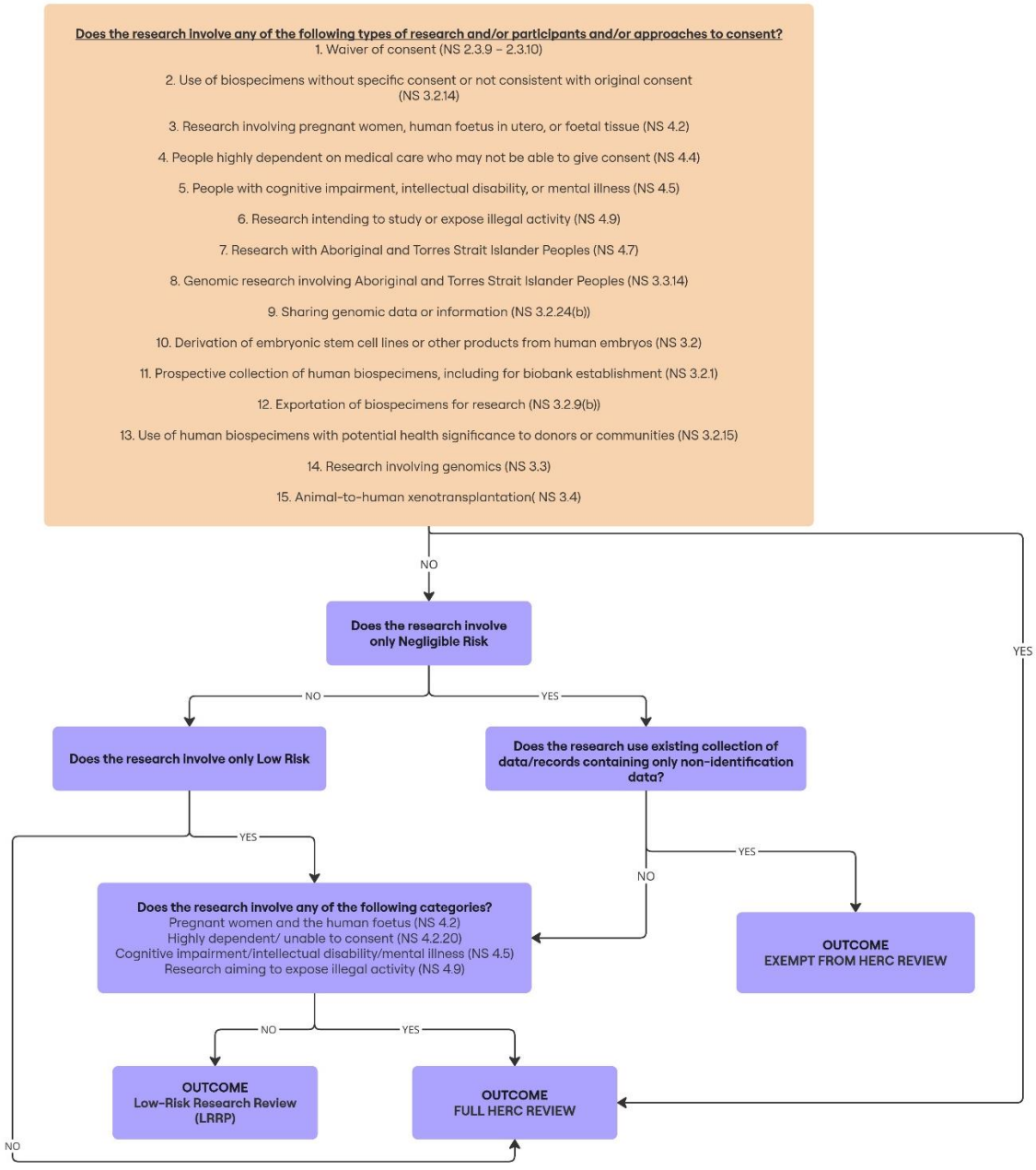
31. The following type of research may be exempted or approved by conditions or recommendations for the ethics review by IHM LR-HREP:

31.1 Includes public datasets and routine administrative records.

31.2 May be exempted from ethics review or reviewed through low-risk pathways if exemption procedures are not defined (i.e., in which the data is not possible to identify such as anonymised data sets that include individuals with dementia, cultural identity etc).

Decision tree for low and negligible risk review

Decision tree for low and negligible risk reviews, with step-by-step guidance to help institutions determine the appropriate level of review.



NOTE: The Institute of Health & Management (IHM) does not have a Human Research Ethics Committee (HREC). All research requiring HREC-level review must be submitted to an external HREC approved under the National Statement on Ethical Conduct in Human Research. IHM supports a Low-Risk Research Panel (LRRP) to review research deemed low or negligible risk in accordance with ethical guidelines.

General Conditions and Restrictions

32. Researchers must adhere to the following general conditions, but are not limited to, for their project to be eligible for ethics review by the IHM-LR-HREP:
    - 32.1 Participants must not be identifiable and must not belong to higher-risk (Greater than low and high) or vulnerable groups, unless safeguards are in place.
    - 32.2 No deception unless specifically justified and approved.
    - 32.3 Privacy, confidentiality, and data security must be maintained.
    - 32.4 Risks and burdens must be clearly outweighed by the potential benefits.

Responsibility and Training

33. The Research and Innovation Manager and the Research Ethics and Integrity Officer/Research and Innovation Coordinator, in collaboration with the Director of Quality Management, are responsible for implementing this Guideline and ensuring compliance with institutional and national ethical standards for low-risk research.
34. The Research and Innovation Manager is also responsible for:
    - 34.1 Providing induction and ongoing training and support to members of the LR-HREP.
    - 34.2 Ensuring that researchers, staff, and students involved in low-risk research are aware of their responsibilities and receive appropriate guidance, resources and training.
    - 34.3 Updating and disseminating the Guideline as necessary, in response to regulatory changes or internal reviews.
35. All individuals involved in the ethics review process must complete relevant ethics and compliance training (such as any training that IHM may recommend) before commencing their duties.
36. Inquiries or requests for information can be addressed to: research@ihm.edu.au.

SECTION 3

Associated Information

Related Internal Documents	• Low-Risk Human Research Ethics Procedure • Research, Scholarship and Publication Framework • Low-Risk Human Research Ethics Panel (LR-HREP) Terms of Reference • 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 • State and territory privacy acts • Any other relevant Commonwealth, state, or territory legislation or guidance
Date Approved	
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Version 1.0	30/05/2025	New Guideline on Low-Risk Research