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

1. Background

IHM has proposed the establishment of a Low-Risk Human Research Ethics Panel (LR-HREP) under the provision of low-risk ethics review pathway guidelines stated in the National Statement 2025 (NS) (Chapter 5.1). The LR-HREP is an alternative pathway to Human Research Ethics Committee (HREC), which is the only forum authorised to grant ethics approvals for higher risk research.

Table 1 below presents the institutional risk factors that are, or may be, involved in the setting up of the LR-HREP at IHM, including identification of the associated risk owners for handling the risk events, existing controls within IHM to mitigate risks, mitigation and action plans to treat the identified risk factors, and checklist/status for monitoring the risk events. The Table also has specific comments (if any) for the risk owners to consider.

2. Risk assessment for IHM LR-HREP

Table 1: Risk assessment for the proposed IHM LR-HREP.

Scope	Risk Factors	Risk Owners	Existing Control (Int.)	Mitigation & Action Plan	Status / Checklist	Comments from Risk Owners
Review Pathway or Exemption	1. Incorrectly classifying research projects, leading to higher risk research being reviewed by LR-HREP. 2. Improperly granting exemptions from ethics review.	Research Ethics and Integrity Manager & Director – Quality Management	IHM Risk assessment criteria and processes for LR-HREP	1. Implement clear referral criteria for transferring projects to an IHM LR-HREP if lower risk is identified 2. Ensure staff making these determinations have the necessary knowledge and research expertise 3. Continual alignment with the National Statement. 4. Perform as much as possible number of scenario analysis containing Low Risk applications	☒ ☒ ☒ ☒	No. 1 will be monitored via Guideline on Low-Risk Research as per National Statement.
Complaint Handling Procedures	3. Not establishing or publicising accessible procedures for receiving, handling, and resolving complaints about researchers, research conduct, or LR-HREP conduct. 4. Failure to handle complaints promptly and sensitively.	Research Ethics and Integrity Manager & Director – Quality Management	IHM Research Register IHM Risk Register IHM LR-HREP ToR IHM Policies relating to complaints and appeals.	1. Clear, accessible, and transparent Appeals Complaint procedure 2. Train admin staff & LR-HREP Panel members on complaint handling processes 3. Identify clear contact persons for complaints 4. Establish processes for independent assessment or referral where appropriate	☐ ☒ ☒ ☒	

Manage Conflicts of Interest	5. Actual and potential conflicts of interest involving the institution, LR-HREP Panel members/advisors, or researchers.	Research Ethics and Integrity Manager	IHM Research Register IHM Risk Register IHM Conflict of Interest Disclosure Framework IHM Conflict of Interest Declarations Form	1. Establish and enforce transparent processes for conflict disclosure for all relevant parties 2. Mandatory conflict of interest declarations upon appointment of members of LR-HREP and for each review 3. Measures for identified conflicts *(e.g., excluding members from discussion/decision-making)* 4. Record all declared conflicts and management strategies in meeting minutes	☐ ☒ ☒ ☒	
Resourcing and Support	6. Compromising the quality and timeliness of ethics review.	Research Ethics and Integrity Manager	IHM LR-HREP ToR And Low Risk Research Review Procedure	1. Regularly review LR-HREP workload and resourcing needs 2. Sufficient administrative support 3. Review panel membership to increase the number if required by growing workload. 4. Ensure sufficient number of research focused faculty for appropriate engagement/governance *in Social Work, Public Health & Nursing (related research areas)*	☒ ☒ ☒ ☒	
Standards and Legislation	7. Failure to ensure the LR-HREP operate in accordance with Legislation, Acts, Laws, Standards, Guidelines, Code from NHMRC, AIATSIS, TEQSA, ARC *(including outside Australia)*	Research Ethics and Integrity Manager, & Director – Quality Management	IHM LR-HREP Guidelines & Procedure; and relevant Review and Application Forms	1. HESF Standard 4.1: Research 2. HESF Standard 5.2 – Academic and Research Integrity 3. Clear criteria for review pathways and exemption (in Guidelines) 4. Regular audits of review processes 5. Training for Panel members and staff on standards and legal requirements 6. Adhere strictly to procedures outlined in Privacy Laws when waiving consent of research participants.	☒ ☒ ☒ ☒ ☒	
Membership and Expertise	8. Failing to ensure the LR-HREP composition meets the NS Requirements *(e.g., gender balance, and qualified external membership).* 9. Lack of access to, or failure to seek, necessary expertise *(scientific, technical, specific participant groups, cultural)* required for	Research Ethics and Integrity Manager	IHM LR-HREP TOR (compliant with National Statement) IHM Policy and Procedure	1. Use open and transparent processes for member appointments 2. Regularly review and refresh membership	☒ ☒ ☒	

	proper review of research proposals, particularly for complex or sensitive areas like genomics or Aboriginal and Torres Strait Islander research.	Director – Quality Management		3. Actively seek external expert advice for proposals requiring specialised knowledge 4. Specifically recruit members with relevant knowledge for research areas like Aboriginal and Torres Strait Islander research 5. Governance induction to, and mentoring for, new members	☒ ☒	
Governance and Procedures	10. Failure to establish and publicize clear ToR and SOPs covering meeting conduct, application review, decision-making, record-keeping, monitoring, complaints, etc. 11. Lack of public institutional policies on ethics review processes, leading to operational inefficiency, inconsistent outcomes, and lack of accountability.	Dean – Governance	IHM LR-HREP ToR	1. Comprehensive ToR, SOPs, Policies & Procedures, Guidelines, Framework, Forms 2. Publicly accessible (*on IHM website*) 3. Communication channels between Research Office & Researchers. (Portal or Email)	☒ ☒ ☒	
Indemnity, Insurance, Compensation	12. Failure to assure legal protection for LR-HREP Panel members for liabilities arising from their bona fide duties, including their protection under IHM insurances.	Dean – Governance Head – P&C Head - Legal	IHM LR-HREP ToR	1. Formalise legal indemnity for all LR-HREP and review body members 2. Develop clear processes for participant compensation in cases of harm due to negligence.	☒ ☒	Our insurances protect our committee members
Ethical Research Culture	13. Failure to ensure researchers are adequately qualified and supervised. 14. Inadequate mechanisms for preventing or handling research misconduct.	Dean – Academics Director – Quality Management Registrar – Academics	LR Human Research Ethics Procedure & Guideline on Low and Negligible Risk Research IHM Research, Scholarship, and Publication Framework IHM Publication Register	1. Senior leadership must champion research integrity 2. Establish and enforce clear policies and procedures for addressing research misconduct 3. Adequate support and training for researchers and supervisors 4. Promote open communication about ethical concerns *(e.g. create SharePoint page)*	☒ ☒ ☒ ☒	

Acronyms Used

AIATSIS Australian Institute of Aboriginal and Torres Strait Islander Studies

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

HESF	Higher Education Standards Framework (Threshold Standards) 2021
NHMRC	National Health and Medical Research Council
TEQSA	Tertiary Education Quality and Standards Agency
ARC	Australian Research Council
NS	National Statement on Ethical Conduct in Human Research 2025

3. Conclusion

Establishment of the LR-HREP is a low-risk item itself. As a proportionate review pathway for lower-risk research, its establishment is specifically allowed by the National Statement. LR-HREP does not need to report directly to external bodies (unlike a registered HREC). However, IHM, as a reputed and high-performing higher education institution, remains subject to comprehensive accountability requirements. This includes ensuring its ethics review processes comply with the NHMRC National Statement, TEQSA requirements, the Australian Code for the Responsible Conduct of Research (2018), Ethical Conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018), and other applicable laws and regulations. Accordingly, IHM is aware of its obligation under the NS to provide adequate resources to the LR-HREP.

Ultimately, LR-HREP's ethical conduct and proper functioning will be subject to oversight by internal IHM bodies, particularly the Academic Board. The presence of qualified and experienced external members on the LR-HREP will ensure the Panel's efficient and transparent functioning.

References (External)

[1] Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS). (2020). AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research. AIATSIS.
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[3] National Health and Medical Research Council. (2014). Ethical considerations in quality assurance and evaluation activities. NHMRC.
[4] National Health and Medical Research Council. (2018). Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. Commonwealth of Australia, Canberra.
[5] National Health and Medical Research Council. (2024). Guidelines approved under Section 95A of the Privacy Act 1988, 2014 (updated 2024). NHMRC Publication reference PR2. NHMRC. (Also referenced as "Guidelines approved under Section 95A of the Privacy Act 1988, 2014")
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[7] National Health and Medical Research Council, Australian Research Council & Universities Australia. (2025). National Statement on Ethical Conduct in Human Research 2025.
[8] NSW Health. (2023). Low and Negligible Risk Research Guideline. Document number GL2023_007. Issued: April 2023. Office for Health and Medical Research.
[9] Tertiary Education Quality and Standards Agency (TEQSA). (2024). Guidance note: Academic and research integrity. Version 2.0 (2 February 2024). TEQSA.
[10] Tertiary Education Quality and Standards Agency (TEQSA). (2024). Guidance note: Research and research training. Version 2.1 (11 December 2024). TEQSA.
[11] The University of Queensland. (2024). Human Research Ethics Lower Risk Panel Terms of Reference. Approved date: 29 April 2024. The University of Queensland.
[12] HESF Domain 4: Research and research training | Tertiary Education Quality and Standards Agency.
[13] HESF Domain 5: Institutional quality assurance | Tertiary Education Quality and Standards Agency.