HUMAN RESEARCH ETHICS PROCEDURE

Category	Procedure		
Review	1 year from date of Approval		
Code	ARP004P		
Contact	policy@imc.edu.au		
Version	**Approval Authority**	**Approval Date**	**Review Date**
2024.11	Deputy President (Education)	20 November 2024	30 September 2025

1. PURPOSE

This procedure outlines the processes for ethical review of human research at the Australian National Institute of Management and Commerce (the Institute or IMC). It should be read in conjunction with the Human Research Ethics Policy.

2. SCOPE

This procedure applies to all the Institute's staff, students and honorary appointments who conduct research that involves human participants. It also applies to members of the RC, and to other staff members involved in ethical review processes.

3. PROCEDURES

3.1 Review Procedures

All human research activities conducted at the Institute must be submitted for ethical review.

The Institute has two pathways and processes of ethical review. The process depends on the level of risk to research participants posed by the proposed research. The two pathways and processes of ethical review are:

1. **Expedited Review by Research Committee (RC) - Ethical Review of Low-Risk Research Process or Minimisation of Ethical Review Processes** apply to either low risk research or research that has been approved via an external RC Review process at another institution. The prescribed form can be obtained by emailing the Chair of the RC.

2. **Full Ethical Review by RC – Ethical Review of Research with Greater than Negligible or Low Risk** is required for Moderate to High-Risk Research. These applications are created via the NHMRC's HREA Form Portal and then downloaded and lodged for review.

In preparing human research applications using prescribed forms, researchers must read and be guided by the National Statement on Ethical Conduct in Human Research to determine the level of risk involved in their research.

Expedited Review by the RC

Human research activities that involve negligible or low risk to human participants are exempted from a full ethical review. Applications undergo expedited review and monitoring by the RC.

Research projects that have already been granted ethics approval at another institution (prior ethical review) are also exempted from full ethical review on condition that evidence of approval along with application documentation is submitted to RC for ratification.

Negligible risk means research which involves accessing existing collections of non-identifiable human data or records.

Low risk means research which involves no foreseeable risk to human participants other than discomfort.

The National Statement provides further details and descriptions of levels of risk. The Institute's Research Committee Terms of Reference provide information on the operation of the RC.

Applying for Expedited Review

- Applications for expedited review must be lodged with the Chair of the RC. Applications can be lodged at any time and may take up to one month to assess, particularly if external expert advice is required.
- No activities involving human research activities can commence until written approval is received from RC. This includes recruitment of participants and data collection.
- Applications for expedited review must be accompanied by documentation, including:
  -research proposal information including evidence of the merit of the project;
  -participant information and consent forms;
  -data collection tools;
  -endorsement from supervisors/peers; and
  -any other specific information which may be relevant to human research ethics assessment and approval.

Conditions of Approval

- The period of approval for projects is normally a maximum of three years. During this period, research activities will be monitored. If considered necessary, the RC may also conduct random audits.
- Researchers are required to submit reports annually, or more frequently if requested by the RC.
- Amendments to initial approval conditions require written approval of the RC and must not commence until approval has been granted.

- Researchers are required to report adverse events or unexpected outcomes to the Chair of the RC as soon as possible.
- Final reports on human research must be lodged with the RC by researchers once data collection is complete and once the project has been completed or discontinued.
- Complaints and non-compliance are managed in accordance with relevant Institute's policies, the National Statement and the Australian Code.

Full Ethical Review by the Research Ethics Committee (REC)

Human research activities with greater than low risk require full ethical review. The RC will identify in the first instance the need for a full ethical review and convene the REC on an as needed basis. The review is conducted by the REC.

Applying for Full Ethical Review

- Applications must be lodged with the Chair of the RC at least three weeks prior to the REC meeting.
- No activities involving human research activities can commence until written approval is received from REC and as endorsed by the RC. This includes recruitment of participants and data collection.
- Applications for ethical review must be accompanied by documentation, including:
  -research proposal information including evidence of the merit of the project;
  -participant information and consent forms;
  -data collection tools;
  -endorsement from supervisors/peers; and
  -any other specific information which may be relevant to human research ethics assessment and approval.

Conditions of Approval

- The period of approval for projects is generally a maximum of three years. During this period, research activities will be monitored. If considered necessary, the REC may also conduct random audits.
- Researchers are required to submit reports annually, or more frequently if requested by the RC.
- Amendments to initial approval conditions require written approval of the REC and must not commence until approval has been granted.
- Researchers are required to report adverse events or unexpected outcomes to the REC as soon as possible.
- Final reports must be lodged with the REC by researchers once data collection is complete and once the project has been completed or discontinued.
- Complaints and non-compliance are managed in accordance with relevant Institute's policies, the National Statement and the Australian Code.

Monitoring of Approved Research

The Institute recognises the importance of ongoing monitoring of approved research projects to ensure continued ethical conduct and adherence to approved protocols. The following monitoring procedures will be implemented:

i. Annual Progress Reports:

Researchers must submit annual progress reports to the RC for all approved projects. These reports should include:

a. A summary of research progress
b. Any changes to the approved protocol
c. Any unanticipated problems or adverse events
d. A list of any publications or presentations resulting from the research

ii. Continuous Monitoring:

Researchers are required to promptly report any of the following to the RC:

a. Proposed changes to the research protocol
b. Unanticipated problems involving risks to participants
c. Complaints from research participants
d. Any breaches of confidentiality or data security

iii. Site Visits:

For projects deemed high-risk or involving vulnerable populations, the RC may conduct site visits or request additional information to ensure compliance with approved protocols.

iv. Final Report:

Upon completion of the research project, researchers must submit a final report summarising the outcomes, any significant findings, and confirming the secure storage or destruction of data as per the approved protocol.

v. Audit of Research Practices:

The RC will conduct annual audits of a sample of approved projects to ensure:

a. Adherence to ethical research practices
b. Proper management of conflicts of interest
c. Appropriate handling of commercially sensitive information
d. Ethical use of organisational data

vi. Continuous Education:

The Institute will provide annual refresher training on research ethics and integrity, with a focus on emerging ethical issues in business research.

The RC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the approved protocol or has been associated with unexpected serious harm to participants. Any such actions will be promptly reported to the Academic Board and relevant regulatory bodies.

3.2 Complaint Procedures

General Principles

- All complaints will be handled with sensitivity, confidentiality, and in accordance with procedural fairness
- The Institute is committed to fostering a culture where concerns can be raised without fear of reprisal

Types of Complaints

Complaints may relate to the ethical review process or allegations of research misconduct

Reporting Complaints

- Any person may report suspected research misconduct. Reports should be made in good faith and with sufficient detail to enable an assessment of the nature and severity of the misconduct
- Complaints regarding research projects approved by RC will be managed in accordance with section 5 of the Institute's Code of Conduct for Research policy and the Australian Code
- The Institute will take steps to protect from retaliation those who report suspected misconduct in good faith.

Continuous Improvement

The Institute will review the outcomes of complaints and investigations to identify any systemic issues and implement improvements to prevent recurrence of similar issues.

4. RELATED DOCUMENTS

i. *Human Research Ethics Policy*
ii. *Code of Conduct for Research*
iii. *Code of Conduct for Students*
iv. *Higher Degree Research Confirmation of Candidature and Progression Review Policy and Procedure*
v. *Higher Degree Research Supervision Policy*
vi. *Higher Degree Research Assessment and Assessment Appeals Policy*
vii. *Research Materials and Data Management Policy*
viii. *Guidelines on Minimum Resources for Higher Degree Research Students*

5. VERSION CONTROL

Historical Version	Approved by	Approval Date
2024.11	Deputy President (Education)	20 November 2024

The Deputy President (Education) oversees the implementation and compliance of this policy & procedure. Please contact the Deputy President's office via - policy@imc.edu.au for any enquiries or clarifications related to this policy.