Human Research Ethics Policy and Procedures

Purpose

This Policy aims ensure that all human research conducted at the Central Institute of Technology and Innovation (the Institute) adheres to ethical and responsible standards, aligning with relevant legislation, regulations, guidelines, and institutional policies and procedures. The purpose of this policy is to safeguard the rights, dignity, and well-being of research participants while promoting high standards of ethical conduct and accountability in all research activities. By establishing clear guidelines and procedures, the Institute aims to foster a research environment that prioritises integrity, transparency, and respect for human subjects.

Scope

This policy applies to all staff and students who conduct scholarship and research activities.

Related Documents

This policy should be read in conjunction with the following Institute documents:

- Risk Policy and Risk Register
- Strategic Plan
- Learning and Teaching Plan
- Human Research Ethics Committee Terms of Reference
- Anti-discrimination Policy
- Equity and Diversity Policy
- Information and Privacy Policy
- Records and Information Management Policy

- Code of Conduct Policy and Procedures
- Student Code of Conduct Policy and Procedures
- Student Grievances, Complaints, and Appeals Policy and Procedures
- Staff Grievances, Complaints, and Appeals Policy and Procedures

All documents referenced in this policy can be accessed via the CITI website.

Definition of Key Terms

The following definitions are drawn from the Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code). For the purpose of this Policy, the following definitions apply:

Term	Definition
Adverse event	An adverse event is an unexpected incident which affects or impacts a participant's welfare and/or the ethical acceptability of the project.
Consent	Consent is a person's or group's agreement to participate in a research study based on adequate knowledge and understanding of relevant material relating to the study and the expectations of their involvement in the study.
Chief Investigator	A chief investigator is the Institute staff member who has overall responsibility for the conduct of the project.
Co-investigator	A co-investigator/s are the other investigators involved in a research project for which ethics approval is sought. External co-investigators may be added to a project if their skills, knowledge, and expertise will be of benefit to achieving the aim of the project. External co-investigators will not

Term	Definition
	receive remuneration for their involvement in a project.
Data	In a human research context, data refers to pieces or groups of information. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes.
Databank	A databank is a systematic collection of data.
External approval	External approval means an ethics approval for human research granted by a non-Institute Research Ethics Committee or other human research ethics review body.
Human research	Human research is broadly defined in the National Statement as research conducted with or about people, or their data or tissue.
Intervention	An intervention is an intentional change in the circumstances of research participants with the aim of evaluating the impact of that change on one or more outcome measures. At the Institute, an intervention can be a change in a procedure or process or a behavioural, educational, or social modification. An intervention may also involve a policy change, a change in service provision, or a change in an approach to the provision of information that is introduced and manipulated, controlled, or directed by the researcher.

Term	Definition
Low risk research	Low risk research is one in which the only foreseeable risk to the participant is one of discomfort.
National Statement refers to the National Health and Medical Research Council (NHMRC)	National Statement on Ethical Conduct in Human Research (as updated). The National Statement provides guidelines for institutions and researchers for the design, conduct, and dissemination of results of human research. The National Statement provides guidelines for the review bodies in the ethics review of research.
Negligible risk research	Negligible risk research is research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.
Research study	A research study aims to create new knowledge and/or use existing knowledge in a new and creative way to generate new concepts, methodologies and understandings to benefit the community.

Policy Principles

Human research at the Institute is to be conducted under the guidance of the National Statement and relevant Institute policies and procedures and is overseen by the Human Research Ethics Committee (HREC) of the Academic Board.

1. Research that involves people and their data will only be undertaken where it is ethical and conducted responsibly.

2. The Institute advocates that all research undertaken should be for the benefit of all members of the community.

3. All human research conducted by the Institute requires prior and appropriate ethics review and approval.
4. All risks involved in human research will be assessed, minimised, and managed to ensure that the welfare and interests of the participants, researchers, and the Institute are adequately protected throughout the research process.
5. The HREC is established in accordance with its Terms of Reference and is responsible for reviewing, and where ethical, approving, and monitoring human research at the Institute in keeping with the National Statement and Institute policy and procedures.
6. The HREC will regularly inform the Audit and Risk Committee (ARC) of the Board of Directors about significant risks and/or incidents related to human research matters.
7. The Institute will provide professional development, resources, processes, and infrastructure that support researchers to understand human research ethics and the gaining and maintaining of human research ethics approval. Professional development will also address the responsible conduct of research that complies with relevant legislation, regulations, guidelines, and Institute policy and procedures.

Policy Statement

The Institute is committed to ensuring that all research involving human participants is conducted in accordance with the highest ethical standards. This Policy and Procedures establish a framework to ensure that research is designed, reviewed, and undertaken with integrity, respect for persons, beneficence, and justice, and in compliance with applicable legislation, regulatory requirements, and recognised ethical guidelines.

Procedures

The following procedures apply to all standard applications related to research studies:

1. Gaining Human Research Ethics Approval

1.1 **Standard Applications for Human Research Ethics Approval:** The Chief Investigator will complete the appropriate Institute Human Research Ethics Application Form and submit it to the HREC, using the forms and instructions provided on the Staff Portal, Learning Management System, and in this policy and procedure. Relevant accompanying and supporting documentation must be submitted with the ethics application form including copies, if applicable, of:

1.1.1 Research instruments (e.g., questionnaire/s, survey/s, and/or proposed interview/focus group outlines).

1.1.2 Participant information and consent form/s.

1.1.3 Recruitment materials (e.g., advertisements, posters, flyers, brochures)

1.2 **Coursework Applications for Human Research Ethics Approval:** An Institute staff member can apply for coursework human research ethics approval for common and clearly defined human research activities that are being undertaken by the staff member and/or students for coursework approvals. These approvals will generally apply for negligible or low-risk applications. Where coursework-related research activities are assessed as more than low risk, the staff member will consult with the HREC regarding the provision of human research ethics approval. Where coursework involves an external party or industry involvement, approval must be sought in writing by the appropriate person within that organisation. Coursework applications will be prepared and submitted by the relevant Unit Coordinator or person responsible for the conduct of the unit. This person will be named as the Chief Investigator on the appropriate Institute Human Research Ethics Application Form. This human research ethics approval covers all students enrolled in the relevant unit or program, to carry out the common and defined research activities, for the designated period approved.

1.3 External Research Approval: Where an Institute staff member has external approval for a research project, the researcher must notify the Institute HREC of this approval and must submit a copy of the letter of approval. The Institute, at the discretion of the HREC, accepts human research ethics approvals from external HRECs that are registered with the NHMRC and accepts multi-centre research proposals where Institute researchers are involved but the Chief Investigator is from another institution.

The Institute retains the authority to approve studies to be undertaken on the Institute premises or involving the Institute community.

2. Identification of Level of Risk

The Institute acknowledges that all research studies have a level of risk. Researchers must identify the level of risk prior to submitting their application for ethics approval.

2.1 **Risk and Risk Assessment:** In line with the National Statement, human research is categorised by the level of risk. There are four categories of risk: a) Exempt from review: research involving secondary analysis of non-identifiable data. b) Negligible risk: research in which there is no foreseeable risk of harm or discomfort. c) Low risk: research in which the only foreseeable risk is one of discomfort. d) More than low risk: research that may lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth, and social disadvantage. At the Institute, the majority of research studies will fall into categories a), b), and c).

2.2 **Ethics Exemption:** Projects that are deemed to be exempt from review will not be required to submit an ethics application. However, any research study that is undertaken by Institute staff and/or involving participants from the Institute community must submit a research proposal and risk assessment to the HREC outlining the research aims, research methods, and the intended outputs. These projects will be assessed and approved by the HREC. Results of exempt studies must also submit an annual review.

2.3 **Negligible and Low Risk:** Ethics applications for research projects that are deemed to be of negligible risk or low risk must be submitted to the HREC. Research studies that are deemed to be negligible or low risk must complete an Institute Human Research Ethics Application Form: Low Risk Category. Negligible and Low Risk research projects are reviewed out of session.

2.4 **More than Low Risk:** Projects that are deemed to be of more than low risk must submit an Institute Human Research Ethics Application Form: Full Review Category to the HREC for approval.

2.5 **Ethics Review and Approval:** The HREC will review all applications for human research ethics at the Institute on behalf of the institution and in line with relevant codes, guidelines, legislation, and Institute policy and procedures:

2.5.1 Submission dates for applications and meeting dates (where applicable) for the HREC are published on the Staff Portal.

2.5.2 Applications that do not meet relevant submission dates or other governance requirements will be held over to a following meeting.

2.5.3 All applications will be vetted for completeness and compliance with governance requirements.

2.5.4 Incomplete, insufficient, and/or unauthorised applications will not be accepted for review.

2.5.5 Relevant ethics training will be completed before applicants apply for ethics approval.

2.5.6 The HREC will inform the Chief Investigator of the outcome of the review in a timely manner.

2.5.7 As per the National Statement, researchers cannot appeal an ethics review body's decision to reject an application.

2.6 **Duration of Approval:** Applications will be approved for a minimum of six months and for a maximum of three years. Extensions can be requested for beyond the initial three-year approval period up to a maximum of five years.

2.7 **Amending a Human Research Ethics Approval:** Amendments are required where researchers plan to vary any aspect of an approved project. This includes changes to the Chief Investigator, research participants, recruitment methods, research methods, research sites/locations, or an extension of approval. Researchers must gain approval for an amendment prior to implementing the change. Requested amendments to an approved project must not be implemented by the Chief Investigator until the request is approved. Researchers must seek approval for an amendment to extend ethics approval before the approval period has expired. Research activities that require ethics approval must not continue when such approval has expired. The Institute Request for Amendment of an Existing HREC Approval Form must be accompanied by all relevant

supporting documentation (e.g., revised participant information sheets or revised interview schedules). Requests for amendment which fail to meet any applicable submission dates will be held over to a future meeting.

3. Ethics Reporting

3.1 **Annual Report:** The Chief Investigator must submit an annual report by the anniversary date of ethics approval for the duration of the approval period. Report templates are made available to researchers on the Staff Portal. The annual reports must detail the project progress over the past 12 months including any progress made towards the objectives of the study and any adverse events or incidents over the reporting period. Ongoing approval of a project is conditional upon the submission of annual reports. Reports are still required even where an approved project has not commenced or has been abandoned. In the final year, the Chief Investigator will submit a final report within six months of the end of the approval period. The final report will provide a conclusion statement on the outcomes of the project or activities and should also outline any publications (either submitted or in progress) resulting from the project or activities and if any further avenues of research have arisen as a result.

3.2 **Adverse Events:** As per the National Statement, any adverse event must be reported promptly by the Chief Investigator to the Chair of the HREC as soon as practicable of it being identified or coming to the attention of the researcher/s. Notifications must be submitted in writing via email. Following notification, researchers will be issued an Institute Human Ethics Adverse Event Report Form to complete, which will include details of the incident and any action taken or that will be taken. The completed Form must be returned to the Chair of the Committee. The Chair, HREC reviews the Form and provides a report to the committee detailing the event, and any findings and recommendations. The Chair will advise the Chief Investigator, line manager, and any other appropriate persons/bodies, as required. A response may be required from the Chief Investigator for reporting purposes.

3.3 **Monitoring and Withdrawal of Ethics Approval:** As per the National Statement, monitoring approved ethics projects is conducted through several mechanisms including annual reports; review of adverse events; ad hoc inspections of projects and

project documents; reports from external partners or industry; and other forms of feedback.

3.4 **Auditing:** The Chair, HREC may request an audit of research projects that have human research ethics approval. Results of any audits will be reported back to the Committee. The HREC may withdraw approval for any project, before or after an audit, when they have reason to believe that the research project continuing would compromise the welfare of participants, researchers, or others involved in the study. Where the Institute HREC withdraws approval for a project, the Committee will notify the researcher/s, as well as the relevant line manager. The Institute HREC may also notify other parties, including participants, where appropriate.

3.5 **Suspension:** Where the HREC considers that suspension of approval for a research project is required before the complaints process is undertaken, they may suspend the research. In reviewing cases of non-compliance or events in which participant welfare has been compromised, the HREC may refer the matter to the Chief Executive Officer for consideration under the Institute Policies and Procedures.

4. Complaints

In the event that there is a complaint raised about a project that is being conducted by an Institute staff member, the HREC will undertake action to address the issue in a manner that is both timely and appropriate.

4.1 The complaint should be lodged with the HREC Chair.

4.2 The Chair will acknowledge receipt of the complaint.

4.3 The Chair will consider the complaint and as appropriate may form a working party to investigate the complaint and report to the HREC.

4.4 The working party will comprise the Chair, two members of the Committee, and any other staff member that may provide support and advice in the investigation. The Chair will prepare a report for the HREC. The report will detail the investigation and any findings and recommendations for further action. The HREC may refer the complaint on to the appropriate institutional process.

4.5 If unsubstantiated, the Chair, HREC will determine that no further action is required. The working party or the Chair will outline the reason/s for the dismissal. This report will be provided to the complainant, and this will be recorded at the next HREC meeting.

4.6 Where investigation finds that the complaint involves a breach of the National Statement, the working party will work with the researchers to avoid a recurrence. This will be recorded at the next HREC meeting.

4.7 Where the investigation finds that the breach of the National Statement may also represent a breach of the 2018 Code or other research misconduct, the working party will refer it to the Chief Executive Officer.

4.8 Where the complaint cannot be freely resolved by open communication between the complainant and the working party, the complaint may be submitted to the Chief Executive Officer. The Chief Executive Officer, or nominee, will undertake further investigation, as necessary, to establish the veracity of the complaint. The Chief Executive Officer, or nominee, will provide a report and recommendations to the HREC.

5. Equality and Minority Groups

5.1 The Institute may refuse approval to any research study that may be seen to have a negative impact upon a particular group or sub-group within the Institute.

5.2 In accordance with the Institute Policies and Procedures, participants in approved research studies should not be exposed to any form of discrimination, harassment, or any form of activity that may make the participant feel disempowered or vilified.

6. Aboriginal and Torres Strait Islander Peoples

6.1 In relation to Institute Policies and Procedures, any proposed research study involving Aboriginal and Torres Strait Islander Peoples will be reviewed and approved by the HREC. Review of research involving Aboriginal and Torres Strait Islander Peoples will include assessment by and/or advice from people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research involving Aboriginal and Torres Strait Islander Peoples.

6.2 Researchers and the HREC will study and apply the values and ethics guidelines contained in the National Statement and other relevant guidance documents including: Guidelines for Ethical Research in Indigenous Studies [AIATSIS]; Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders [NHMRC] including the six core values of: Spirit and integrity, Cultural continuity, Equity, Reciprocity, Respect, and Responsibility.

7. Monitoring, Review and Recording

7.1 The HREC will monitor and update the Human Ethics Research Policy and Procedures annually in line with any changes to the relevant legislation and standards related to human research and ethics.

7.2 The HREC will also regularly inform the Audit and Risk Subcommittee (ARSC) of the Board of Directors about significant risks and or incidents related to human research matters.

7.3 The Academic Board will receive an annual report of the work of the HREC in accordance with the Academic Board Work Plan and will review and update the HREC Terms of Reference and the effectiveness of the HREC in line with the protocols of the AAEG Board Charter and the National Statement.

7.4 The Chair, HREC is responsible for recording all of the HREC documents in accordance with the Records and Information Policy and for advising and updating the Committee members in relation to the implications of the Privacy Policy.

Related Legislation

This policy should be read in conjunction with the following related documents:

- Higher Education Standards Framework (Threshold Standards) 2021
- Education Services for Overseas Students Act 2000
- Australian Qualifications Framework

- National Health and Medical Research Council (NHMRC), Australian Research Council and Universities Australia: Australian Code for the Responsible Conduct of Research, 2018

Change and Version Control

Version	Date Approved	Authored by	Approved by	Description
1.0	28/08/2024	Chief Executive Officer	Academic Board	Academic Policy

Policy Information

Author	Chief Executive Officer
Responsible Officer	Dean
Approved by	Academic Board
Approval date	28/08/2024
Status	Approved (Current version)
Next review due	28/08/2027

Name of Policy	Human Research Ethics Policy and Procedures	
Version	V1.0	
Policy: Academic	Date: 28/08/2024	Status: Final ratified by the Academic Board on 28/08/2024

File: Human Research Ethics Policy and Procedures_V1.0