

## 1. POLICY STATEMENT AND PURPOSE

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This policy is intended to provide a research ethics management process at ICHM in compliance with the [National Statement on Ethical Conduct in Human Research \(2007\)](#) (National Statement), [Australian Code for the Responsible Conduct of Research \(2018\)](#) (Australian Code) and [Management of Data and Information in Research](#).

## 2. SCOPE

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This policy applies to all academic staff and students at ICHM

## 3. DEFINITIONS

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- [National Statement on Ethical Conduct in Human Research](#) is a guideline developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia for ethical conduct of research involving human participants.
- [Australian Code for the Responsible Conduct of Research](#) means the code of practice developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia as a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.
- [Management of Data and Information in Research](#) is a guide supporting the Australian Code for the Responsible Conduct of Research developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia for ethical conduct of research involving human subjects for responsible management of data and information in research.

## 4. POLICY

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ICHM is committed to promoting responsible research, which is conducted through a research ethics management process and ensures that:

- research is ethically designed and conducted by researchers (staff, students, research supervisors) in accordance with the Australian Code and National Statement.
- research is reviewed and approved in accordance with processes complying with the requirements of the National Statement.
- approved research is monitored regularly so that the degree of risk to research participants is effectively managed in accordance with the risk level approved.
- mechanisms of reporting are established so that adverse events or unexpected risks for prompt action are identified and acted upon appropriately.

Research within ICHM involving human participants must be approved through the research ethics review process established for ICHM (See Appendix I). ICHM's Research Ethics Committee (ICHM REC) is responsible for the management of ICHM's ethical review processes outlined in this policy. The ICHM REC reports to ICHM's Academic Board, and the Chair of the ICHM REC reports to the Program Director Academic. The Chair

of the ICHM REC or the designated member of the ICHM REC (if the Chair is in conflict of interest) is authorised to approach the Program Director Academic directly if a potential conflict of interest is considered.

## 5. PROCEDURE

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### 5.1 General principles of responsible research

ICHM provides a safe research environment and is committed to a high standard of research excellence by adhering to the National Statement, Australian Code and the Management of Data and Information in Research. Researchers (staff, students, research supervisors) within ICHM are expected to conduct research in full compliance with the aforementioned regulatory obligations.

Individual researchers (staff, students, research supervisors) must identify, gauge, minimize, and manage the risks involved in their research, particularly in relation to the research participants. The ICHM REC is responsible for assessing the risk of the research project taking into account the types of harm, discomfort, or inconvenience that may occur; the likelihood of these occurring; and the severity of any harm that may occur to research participants. Potential harm in research may include (but is not limited to) physical harm; psychological harm; devaluation of personal worth; social harm; economic harm, and legal harm. The research ethics review process set out by the ICHM REC aims to:

- protect the welfare and rights of participants in research.
- ascertain the ethical risk levels of the research.
- preserve the confidentiality and identity of participants and organisation/s involved in the research.
- consider ethical implications and of all proposed research projects involving human participants submitted to it by staff and students of ICHM and to determine whether or not they are acceptable on ethical grounds. These considerations will be based on National Statement, the Australian Code and the Management of Data and Information in Research.
- maintain a record of all proposed research projects in accordance with National Statement.
- monitor research projects which have been approved by the ICHM REC, including the oversight of the storage and management of storage for data.
- maintain a record of all reports on ethical compliance of completed projects.
- consider any other matter relevant to human research ethics referred to it by members of the ICHM community.

### 5.2 Review Process

Research projects will be classified according to the following three levels of ethical risk and will be subject to different review processes (see Appendix I).

- **Level 1 (L1):** Research projects are classified as **Negligible risk** if there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience. "Negligible risk" projects will be assessed through expedited ethical review by the Chair of the ICHM REC or a member of the ICHM REC designated by the Chair.
- **Level 2 (L2):** Research projects are classified as **Low risk** if the only foreseeable risk is one of discomfort. "Low risk" projects will be assessed by a panel of minimum two (2) ICHM REC members, which includes the Chair of the ICHM REC or designated representative of the Chair of the ICHM REC. The Chair may also seek external expert advice as required.
- **Level 3 (L3): All other research** is classified as greater than low risk and is not considered to be appropriate at ICHM. Level 3 projects will not be approved.

The level of ethical risk will be determined by the applicant's responses to questions contained in the Ethics Consideration Checklist, which is included in the research ethics application. The principal investigator/research supervisor of the research project is required to indicate the level of ethical risk in their application clearly. Research is deemed ethically acceptable so long as it satisfies the following two conditions:

1. The level of ethical risk is considered L1 – Negligible; or L2 - Low by the Chair of the ICHM REC or the ICHM REC; and
2. Its potential benefits justify any risks (potential and/or actual) involved in the research.

### **5.3 Student project approvals**

The ICHM REC may grant ethics approval for subjects in which a cohort of students is undertaking short duration research projects. All student projects must be overseen by a research supervisor.

Student projects involving human participants will be subjected to the same ethics review process (including risk assessment) as other applications on the level of risk. However, consistent with the guidelines outlined in the National Statement, student research projects should involve a minimum possible number of human participants and expose them to negligible ethical risk.

Students involved in a research project are responsible for:

1. Submitting their Research Ethics Application to the ICHM REC.
2. Addressing review comments/concerns and revising the Research Ethics Application accordingly.
3. Preserving the confidentiality and identity of participants and organisation/s involved in the research.
4. Providing evidence of responsible conduct of research and compliance with ethical requirements during the research process.
5. Ensuring safe storage and management of research data.
6. Reporting any adverse events or unexpected risks as soon as they become aware of these issue to their research supervisor.

The research supervisor(s) is/are responsible for signing off on the submission of students' Research Ethics Applications to the ICHM REC for approval and ensuring subsequent compliance with approval conditions. To gain ethics approval for a specific student project, the research supervisor is required to adhere to the following steps:

1. Review and assess the ethical risk associated with a student project.
2. Approve the Research Ethics Application(s) of a student project before the student submits this to the ICHM REC for approval.
3. Communicate the ICHM REC review decision in a timely manner to the student.
4. Monitor the research process with evidence of effective risk management (i.e., informed consent, appropriate research instrument, sound stewardship of research data and materials, etc.).
5. Oversee the safe storage and management of research data.
6. At the conclusion of the research, prepare a short report summarising the ethical compliance of the student project(s) under supervision and submit this to the ICHM REC for their records.
7. Report any adverse events or unexpected risks as soon as they become apparent to the ICHM REC for prompt action.

### **5.4 Complaints process**

Any complaints relating to research projects approved by the ICHM REC or any complaints about the conduct of the ICHM REC or decisions made by the ICHM REC should be directed to the Chair of the ICHM REC. In the event of a complaint being submitted, the Chair of the ICHM REC will organise a meeting with the ICHM REC members to review the nature and severity of the complaint. Depending on the nature and severity of the complaint, the Chair may designate an ICHM REC member to investigate the matter in consultation with the appropriate parties (chief investigator, research supervisor, etc.) or involve external academics to investigate

the complaint in order to seek an equitable outcome. The investigation outcome will be reviewed and recorded in the minutes of the ICHM REC meeting. The Chair of the ICHM REC will notify the complainant about the outcome of the investigation. If dissatisfied with the outcome, the complainant may further appeal to the Program Director Academic of ICHM regarding the outcome of the ICHM REC investigation in accordance with ICHM's Academic/Non-Academic Grievance Policies.

## 6. RESEARCH DATA MANAGEMENT

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In accordance with the requirements of the Management of Data and Information in Research guidelines, researchers (academic staff, students and research supervisors) at ICHM must ensure that data and materials generated and collected as part of their research, regardless of the format, are stored securely in a durable and accessible form. Data must be stored in a manner that ensures its authenticity and integrity as well as meeting all legal and confidentiality requirements for a duration of 2 years for short duration student projects and a duration of 5 years for published research. Research data must be backed-up regularly to protect against several risks, including human error, hardware failure, software faults, and power outages. ICHM provides secure, password protected cloud-based storage for staff and students to back up critical research data and materials. Staff and student researchers are responsible for the management of safe storage and backup of their research data, which is only accessible to the investigators (students and their research supervisors) of the research project.

## 7. SUPPORTING DOCUMENTATION

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The links to the supporting documents mentioned in this policy are available at:

- [Australian Code for the Responsible Conduct of Research;](#)
- [National Statement on Ethical Conduct in Human Research;](#)
- [Management of Data and Information in Research](#)

The internal supporting document includes:

- *Research Ethics Committee Terms of Reference*

## 8. ACKNOWLEDGEMENTS

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ICHM acknowledge reference to the following sources of information in the development of this policy:

- [Charles Darwin University 2018, Program Ethics Approvals](#)
- [Charles Darwin University 2018, Responsible Conduct Research Policy](#)
- [University of South Australia 2018, Human Research Ethics Policy](#)
- [Swinburne University 2018, Research Data Management](#)

## 9. RESPONSIBILITIES AND AUTHORITIES

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The Policy Owner is the Program Director Academic of ICHM. The ICHM REC is responsible for the quality, currency and implementation of the Research Ethics Policy. The Academic Board is the approval authority of the Research Ethics Policy.

## 10. AMENDMENTS AND REVIEW

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The ICHM REC is responsible for the review of the Research Ethics Policy on a yearly basis. The ICHM REC may make recommendations to the Academic Board for amendments to the Research Ethics Policy.

## 11. APPROVAL

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<b>Research Ethics</b>	
<b>Owner</b>	Program Director Academic
<b>Version Number</b>	2.0
<b>Approval Authority</b>	Academic Board
<b>Approval Date</b>	15 June 2021
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<b>Date</b>	<b>Version</b>	<b>Modification</b>	<b>Approval Authority</b>	<b>Approved &amp; Published</b>
August 2020	1.0	Policy Creation	Academic Board	Sept 2020
June 2021	2.0	Minor amendments to responsibilities due to ICHM restructure.	Academic Board	Approved at AB 15/06/2021

## Appendix I Research Ethics Review Process by the Research Ethics Committee

