Human Research Ethics Policy

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1   PURPOSE

The Institute promotes ethical conduct in all research activities. This policy is concerned with the principles and practices relevant to the design, review and conduct of human research.

The purpose of this policy is to provide clarity regarding assessment of research risk and benefit, and ethical review processes. The composition and terms of reference of the Human Research Ethics Committee (HREC) is articulated as well as the responsibilities of THE INSTITUTE, and THE INSTITUTE's researchers and research supervisors, including staff, students and honorary appointments.

This Policy complies with the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research.* It should be read in conjunction with other relevant documents in THE INSTITUTE's Research Policy Framework (see related documents in Section 5).

2   SCOPE

This policy applies to all the Institute's staff, students and honorary appointments conducting research that involves human participants. It also applies to members of the HREC, to members of the HDRSC, and to other staff members involved in ethical review processes.

3   DEFINITIONS

Australian Code for the Responsible Conduct of Research (Australian Code) is a code developed by the National Health and Medical Research Council and Universities Australia. (file:///C:/Users/TOP%20IT/Downloads/The-australian-code-for-the-responsible-conduct-of-research-2018%20(1).pdf)

Higher Degree, Research and Scholarship Committee (HDRSC) is the principal advisory committee of the Academic Board on issues of research. HDRSC has responsibilities for two key areas at the Institute: research; and higher degree research and training.

Human research is any research with or about human participants, including their data or tissue. Examples of human research most likely to be relevant to research activities at THE INSTITUTE include: surveys and questionnaires; interviews; focus groups; access to individuals' information; and behavioural testing and observation.

Human Research Ethics Committee (HREC) is a committee established to take responsibility for THE INSTITUTE's ethical review processes for research involving humans.

National Statement on Ethical Conduct in Human Research (National Statement) is a statement released by the Australian Research Council and National Health and Medical Research Council. (https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)

Research is defined in the Australian Code as follows:

> *The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative* (p.5).

4 PROCEDURES

4.1 Principles of Ethical Human Research

The Institute requires that human research design be based upon sound approaches and methodologies, and that research be conducted by researchers who have the requisite skills, knowledge, experience, resources and facilities.

Researchers and those involved in review processes must be aware of the ethical values and principles in the *National Statement* and they should be addressed in the design, review and conduct of human research. These four values and principles are summarised below.

  i.   *Research merit and integrity* – to justify the involvement of human participants, the research project must have merit and researchers must have integrity.

  ii. *Justice* – human participants must be treated fairly and not have any undue burdens placed upon them.

  iii. *Beneficence* – researchers must reflect on the social and cultural significance of their research and consider the benefits to participants and their communities.

  iv. *Respect* – research must respect and value each participant and this value must inform all interactions with participants.

There is an expectation that researchers will use these values and other guidance material such as THE INSTITUTE's *Research Code of Conduct Policy* and the *Australian Code* in a manner that is mindful of the welfare of participants.

4.2 Responsibilities

Institutional responsibilities

The Institute is required to:

i. Provide induction and continuing education to staff and students on human research ethics;

ii. Establish and monitor relevant review bodies to consider applications and report on the conduct of human research activity as stipulated by the *National Statement*; and

iii. Have processes for: managing conflicts of interest; monitoring research; handling complaints; and ensuring accountability.

Researcher responsibilities

Staff and students conducting research are required to:

i. Conduct research ethically, in accordance with the *National Statement* and THE INSTITUTE's Policies and Codes;

ii. Seek and obtain approval for all human research activity and comply with conditions of the approval;

iii. Notify the appropriate review body of any adverse events or unexpected outcomes arising from human research activity; and

iv. Ensure records of research activities are maintained and regular reports are provided to the relevant review body.

4.3 Review processes

There is a requirement that all human research activities conducted at THE INSTITUTE be submitted for ethical review.

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

The two pathways and processes of ethical review are:

1. **Expedited Review by Higher Degree, Research and Scholarships (HDRSC) - 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 HREC Review process at another Institution. The prescribed form can be obtained by emailing the Chair, HDRSC.

2. **Full Ethical Review by Human Research Ethics Committee (HREC) – 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 their applications using prescribed forms, researchers must read and be guided by the National Statement on Ethical Conduct in Human Research (2007) (NS) to determine the level of risk involved in their research. The first two sections of the National Statement are particularly important and relevant.

4.3a) Expedited Review by Higher Degree, Research and Scholarships Committee (HDRSC)

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

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 HDRSC for ratification.

The levels of risk are categorised as follows:

> *Negligible risk* – Involves accessing existing collections of non-identifiable human data or records.

> *Low risk* – Has no foreseeable risk other than discomfort.

See the *National Statement* for further details and descriptions of levels of risk. Also refer to THE INSTITUTE's Higher Degree, Research and Scholarship Committee Terms of Reference for information on this committee's operations.

Applying for Expedited Review

- All human research projects undertaken at THE INSTITUTE that involve negligible or low risk will require approval by HDRSC. Applications may be lodged with the Chair, HDRSC at any time and may take up to one month to assess, particularly if external expert advice is sought on the application.
- Human research activities must not commence until written approval is received from HDRSC. 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.

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 HDRSC or the HREC may also conduct random audits.
- Researchers are required to submit annual reports, or more frequently if requested by the HDRSC or the HREC.
- Amendments to initial approval conditions require written approval of the HDRSC and must not commence until approval has been granted.
- Researchers are required to report adverse events or unexpected outcomes to the Chair of the HDRSC.
- Final reports must be lodged with the HDRSC 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*.

4.3b) Full Ethical Review by Human Research Ethics Committee (HREC)

A full ethical review of activities with greater than low risk is conducted by the Human Research Ethics Committee (HREC). Projects with negligible or low risk may be referred to HREC for a full ethical review by the HDRSC if considered appropriate.

Applying for Full Ethical Review

- All human research projects undertaken at THE INSTITUTE with more than low risk must be approved by the HREC. Applications must be lodged at least three weeks prior to a HREC meeting.
- Human research activities must not commence until written approval has been received from HREC. 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.

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 HREC may also conduct random audits.
- Researchers are required to submit annual reports, or more frequently if requested by the HREC.
- Amendments to initial approval conditions require written approval of the HREC and must not commence until approval has been granted.
- Researchers are required to report adverse events or unexpected outcomes to the HREC.
- Final reports must be lodged with the HREC 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.*

4.5 Human Research Ethics Committee (HREC)

Composition

The HREC is composed of a minimum of eight members and conforms with requirements of *National Statement.* Membership is as follows:

a. Chairperson who has relevant experience;
b. two lay-persons, one male and one female, with no affiliation to THE INSTITUTE and who are not currently involved in research activity;
c. one person with no affiliation to THE INSTITUTE with experience in the care of people;
d. one person with a pastoral care role in the community;
e. a lawyer not engaged to advise THE INSTITUTE; and
f. two people with current, relevant research experience.

The Institute aims to include approximately equal numbers of male and female members with one third of the members having no other affiliation to THE INSTITUTE.

The composition of the HREC may vary to best accommodate the needs of specific research projects. For example, where participants include Aboriginal and Torres Strait Islander peoples, an aboriginal elder must be appointed.

Appointment procedures

Members of HREC are nominated by the HDRSC and submitted to the Academic Board for approval. The appointment of members is for a period of three years. Following review, members may be reappointed.

Terms of Reference of HREC

- Protect the rights and welfare of participants in human research activities;
- Review proposed human research projects that involve more than low risk and other proposals referred by HDRSC;
- Consider ethical implications and make decisions on whether or not human research proposals are satisfactory based on requirements of the *National Statement on Ethical Conduct in Human Research;*
- Forward, as required, a report on decisions to the appropriate research funding authority;
- Monitor approved research projects and maintain records of approved protocols;
- Report to HDRSC and Academic Board as required;
- Receive and manage disclosures of conflict of interest;
- Receive and investigate complaints concerning human research ethics; and
- Make recommendations to HDRSC and other appropriate staff and be available for consultation on human research ethics.

4.6 Complaints

All complaints will be handled with sensitivity and confidentiality.

Complaints regarding allegations of research misconduct are handled in accordance with THE INSTITUTE's Research Code of Conduct and the Australian Code.

The Chair of THE INSTITUTE's HREC, or in the absence of the Chair an independent external expert appointed by the Principal, will investigate any complaints relating to the ethical review or ethical conduct of research.

Complaints regarding research projects approved by HDRSC or HREC should be directed to the Chair of the HREC or the Principal.

5 RELATED DOCUMENTS

   i.   Code of Conduct for Research
  ii.   Code of Conduct for Students
 iii.   Research Higher Degree Confirmation of Candidature and Progression Review Policy
  iv.   Research Higher Degree Registration and Roles of Supervisors Policy
   v.   Research Higher Degree Assessment and Appeals Policy
  vi.   Research Support Guidelines
 vii.   Research Materials and Data Ownership, Storage, Retention and Disposal Policy
viii.   Minimum Facilities for Postgraduate Research Students Policy

6 Version Control

Historical Version	Approved by	Approval Date
2013.12	Academic Board	19 December 2013