

Human Research Ethics Policy

Section 1 - Purpose

(1) This Policy outlines how Macquarie University fulfils its responsibilities for ensuring compliance with applicable codes, policies and guidelines for research involving humans.

Background

(2) Research involving humans, conducted under the auspices of Macquarie University (the University), must meet the expectations endorsed in the [National Statement on Ethical Conduct in Human Research](#) (the National Statement) and the [Australian Code for the Responsible Conduct of Research](#) authored by the National Health and Medical Research Council (NHMRC), the [Australian Research Council \(ARC\)](#) and [Universities Australia](#) (UA).

(3) The National Statement defines human research as research conducted with or about people, or their data or biospecimens. Human research includes:

- a. taking part in surveys, interviews or focus groups;
- b. undergoing psychological, physiological or medical testing or treatment;
- c. being observed by researchers;
- d. researchers having access to their personal documents or other materials;
- e. the collection and use of their biological material as defined in the National Statement; and
- f. access to their individual information in identifiable or potentially re-identifiable form as included in an unpublished source or database that is used for human research.

(4) The National Statement notes that the term “participants” is used very broadly to include those who may not even know they are participating in research (for example, where the need for their consent for the use of their biospecimens or data has been waived by an ethics review body).

Scope

(5) This Policy applies to any person (or persons) who conducts or assists with the conduct of human research under the auspices of Macquarie University. This may include staff members (academic and professional), visiting students, visiting fellows, volunteers, honorary and adjunct title holders, Emerita/us Professors, and occupational trainees who conduct or assist with the conduct of research at or on behalf of the University. This includes contracted/commercial research.

(6) This Policy also applies to Graduate student research and Honours student research, as well as other student related research activity, when such activity forms the research component of any degree or award for which research equates to a minimum 25 per cent of the entire degree or award.

Section 2 - Policy

(7) The University is committed to conducting research with the highest standards of ethics and accountability, to foster a robust and trustworthy research culture.

(8) The University will:

- a. establish systems and processes to foster adherence to the applicable codes, policies and guidelines for all research involving human participants;
- b. promote research that respects research participants and extends benefit to the community;
- c. assist researchers in the design and conduct of their research to comply with relevant legislation, policies and guidelines;
- d. provide training for researchers undertaking human research; and
- e. maintain Human Research Ethics Committees (HRECs) and sub-committees of the HREC to undertake human ethics reviews per the National Statement.

(9) Researchers must ensure that:

- a. the ethics principles of research merit and integrity, justice, beneficence and respect are applied to human research as set out in the National Statement;
- b. approvals to conduct human research are obtained prior to the commencement of research. Retrospective ethics approval will not be considered;
- c. all other required processes, institutional approvals or authorisations, including risk management, are completed or granted prior to the commencement of the research;
- d. conditions of any approvals are adhered to throughout the conduct of the research;
- e. appropriate engagement occurs with communities and/or consumers that are relevant to the research; and
- f. they engage responsibly with ethics review, governance and monitoring processes.

Training

(10) Researchers must complete mandatory human research ethics training prior to submitting their proposal for human research ethics review.

Research proposals

(11) Researchers requiring approval of their research via the University human research ethics review process must:

- a. submit an application for their project for:
 - i. human research risk review; and/or
 - ii. human research ethics review, if the risk level of the project is known to be either low or greater than low risk;
- b. identify only one Chief Investigator (CI)/Principal Investigator (PI) for each project who takes overall responsibility for the research, who is:
 - i. a continuing staff member of Macquarie University; or
 - ii. a fixed term staff member or external to the institution only with permission via the ethics.secretariat@mq.edu.au.

(12) Researchers collaborating with third parties to conduct research must notify the University of the arrangements for human research ethics review and approval whenever data will be collected or participants recruited at the University (as detailed in clause 24).

Use of Artificial Intelligence

(13) Artificial Intelligence (AI) tools, including Generative AI may be used to support or enhance the preparation of ethics applications. Their use must strictly comply with the [Responsible and Ethical Use of Artificial Intelligence Policy](#),

national guidelines and sector standards.

(14) Researchers must maintain human oversight and are wholly responsible for the accuracy, integrity, and ethical acceptability of any application materials produced with the assistance of Generative AI.

(15) Substantial use of Generative AI (for content creation, analysis, idea generation, or synthesis) must be clearly disclosed in the ethics application, specifying the type of AI tool used and its role. Disclosure is not generally required for minor editorial support (e.g., grammar correction) but is mandatory when AI meaningfully affects the research design or the narrative.

Conflict of interest

(16) Researchers and committee members must declare and manage any actual, potential or perceived conflict of interest, including any financial or other interest or affiliation that relates to the research, per the [Conflict of Interest Policy](#).

Research primarily involving Aboriginal and Torres Strait Islander peoples

(17) Researchers planning to undertake research primarily involving Aboriginal and Torres Strait Islander people and communities must ensure that they consult and follow the advice in the most contemporary versions of the following:

- a. [NHMRC's Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders](#) (2018);
- b. [Keeping Research on Track II](#) (2018);
- c. [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research](#) (2020); and
- d. [A Guide to Applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research](#) (2020) produced by the [Australian Institute of Aboriginal and Torres Strait Islander Studies](#) (AIATSIS).

Data management

(18) All data collection, storage, retention, disposal, sharing and re-use must follow the procedures specified in the researcher/s ethics approved application.

(19) Researchers must maintain comprehensive records of their research in accordance with their approved protocol and/or their data management plan, as required by the National Statement and in compliance with the University's [Research Data Management Policy](#).

(20) Potential Data Breaches must be managed per the [Data Breach Policy](#). A notification of any potential data breach must also be made to the relevant HREC or its sub-committee.

Conduct of approved projects

(21) Researchers must:

- a. promptly report any adverse events, project deviations or unforeseen ethical issues to the relevant Human Research Ethics Committee or sub-committee; and
- b. comply with monitoring and reporting requirements as stipulated by the Human Research Ethics Committees or its sub-committees.

(22) Proposed amendments to an approved project:

- a. can be submitted at any time by using correspondence in project via the [FoRA System](#); and
- b. cannot be implemented until approved by the appropriate Human Research Ethics Committee or its sub-

committee.

Research outputs

(23) In research outputs associated with human research ethics review, researchers must include a statement identifying the institutional or licensing committee that reviewed the research. This statement must include the relevant code for the approved project/protocol.

Research approved by an External Ethics Committee

(24) The University may accept approval from an external ethics review body in accordance with the requirements of the National Statement, for research that will involve the collection of data or recruitment of participants at the University, provided that:

- a. Macquarie University is listed as an approved site for the research;
- b. Macquarie University researchers are named on the application;
- c. researchers provide evidence of ethics approval prior to the commencement of any research; and
- d. for research approved by an International Ethics Review Body (IERB):
 - i. a copy of the applicable National Standards or ethics framework under which the IERB conducted its review is provided; and
 - ii. equivalent ethical standards to the National Statement can be demonstrated, based on the principles of research merit and integrity, justice, beneficence, and respect for human beings.

(25) The Human Research Ethics Secretariat will initially assess IERB approvals. If their acceptability is unclear, or if the IERB doesn't meet the criteria above, the researchers may be asked to submit their project for additional ethics review at the University.

(26) Research that has already received or is being submitted for approval from the HREC of another institution, or from an IERB, requires an additional Macquarie University ethics review if researchers are collecting data or recruiting participants at the University but the University is not listed as an approved site.

Monitoring of approved research

(27) The University and the HRECs may employ a variety of approaches to monitor approved research and to verify compliance. This may include internal reviews of documentation, inspection of sites and/or interviews or meetings with researchers and research participants.

Compliance and Breaches

(28) Alleged breaches of this Policy and non-compliance by a researcher will be managed in accordance with the [Macquarie University Research Code Complaints, Breaches and Investigation Procedure](#) (the Research Code Procedure).

Institutional reporting

(29) The University will provide annual reports, inter alia, to the [NHMRC](#) and reports waivers of consent annually to the [Information and Privacy Commission NSW](#).

Ethics review services for third parties

(30) Subject to the availability of resources and capacity, and at the discretion of the Director, Research Ethics and Integrity, the University may provide ethics review services to third parties, generally on a fee-for-service basis, in

accordance with the [Macquarie University HREC published fee schedule](#). Factors taken into consideration may include whether:

- a. the proposed research aligns with University research priorities, policies, and values;
- b. the University has an existing contractual agreement or formal arrangement with the third party; and
- c. the third party demonstrates they do not have access to an appropriately constituted HREC within their own organisation.

External research involving Macquarie University staff or students

(31) The University receives requests to access staff and students at the University as research participants. While the University supports legitimate research that contributes to knowledge and benefits the community, it must ensure appropriate governance processes are in place to protect staff and students.

(32) Any request to access staff and students at the University as research participants must have approval from their host institution's HREC or IERB. The requirement for additional University approval depends on the scale and scope of the proposed research, as follows:

- a. Research involving no direct contact with staff or students does not require separate approval from the University. For example, a single online survey that is not specifically targeting staff or students and is not advertised via University-specific communication channels or on University premises.
- b. Extensive research involving multiple data collection points, face-to-face interactions, access to University facilities, or targeting of specific cohorts of staff or students will require approval via the appropriate School or Faculty.

(33) The considerations for approval of any external research request to access University staff or students, may include whether the research:

- a. aligns with University priorities and academic objectives;
- b. ensures adequate protection of staff or student wellbeing; and
- c. provides for compliance with the applicable privacy legislation.

Section 3 - Procedures

(34) Nil.

Section 4 - Guidelines

(35) Nil.

Section 5 - Definitions

(36) The following definitions apply for the purpose of this Policy:

- a. Generative Artificial Intelligence (Gen AI) is a subset of Deep Learning and a wide-ranging term that refers to any form of artificial intelligence capable of generating new content, such as text, images, video, audio or code (New South Wales Government's Generative AI: Basic Guidance).
- b. IERB refers to an International Ethics Review Body that reviews research for ethics compliance.
- c. National Health and Medical Research Council ([NHMRC](#)) is Australia's peak body for supporting health and

medical research; for developing health advice for the Australian community, health professionals and governments; and for providing advice on ethical behaviour in health care and in the conduct of health and medical research.

- d. National Statement is the [National Statement on Ethical Conduct in Human Research 2023](#). The National Statement clarifies the responsibilities of institutions, researchers and review bodies for the ethical design, review, conduct, and dissemination of results of human research.

Status and Details

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