Human Research Ethics Procedure

Section 1 - Purpose and Scope

(1) The University of Queensland (UQ or the University) is committed to promoting a culture of responsible and ethical research. Where research involves or is about humans, their tissue or data, researchers have specific obligations to ensure that all ethics approvals are obtained prior to the work commencing. This Procedure describes the processes for obtaining UQ ethics approval for human research.

(2) This Procedure should be read in conjunction with:

a. Responsible Research Management Framework Policy; and
b. National Statement on Ethical Conduct in Human Research (National Statement).

(3) Staff and students at the University are required to conduct themselves in a manner consistent with the Australian Code for the Responsible Conduct of Research 2018, the National Statement, and the standards set out in the relevant UQ code or charter:

a. Staff and Title Holders: Staff Code of Conduct Policy.
b. Students: Student Code of Conduct Policy.
c. Higher Degree by Research (HDR) candidates: Higher Degree by Research Candidature Charter Policy.

(4) This Procedure applies to all staff, students and title holders who conduct, or assist with the conduct of, human research at, or on behalf of, UQ.

(5) Researchers external to the University who wish to conduct research at UQ must contact Research Ethics and Integrity for direction and assistance in obtaining gatekeeper approval.

Section 2 - Process and Key Controls

(6) To be ethically acceptable, human research must comply with the National Statement and demonstrate the values of research merit and integrity, justice, beneficence and respect.

(7) Research involving Aboriginal and Torres Strait Islander Peoples must also be conducted in accordance with:

a. NHMRC - Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders;
b. NHMRC - Keeping Research on Track II; and
c. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research.

(8) All research involving or about humans, their tissue or data must be subject to ethics review or qualify for an exemption from review. Applications must be made through MyResearch.

(9) Approval is generally provided for a maximum period of 5 years duration, provided all annual reports are submitted. Substantial changes to approved projects will usually require submission of a new application and not be

approved via the amendment pathway.

(10) All human research must:

a. commence only after approval or ratification has been granted, or conditions for exemption established;
b. be conducted in accordance with the approval;
c. cease if approval or ratification is suspended or withdrawn; and
d. be subject to monitoring.

(11) Complaints will be handled through the appropriate University process as outlined in clauses 28-30 of this Procedure.

Section 3 - Key Requirements

Part A - Human Research Ethics Review Pathways

(12) The University has established different pathways for human ethics review. The level of review required is primarily determined by the risks involved in the research. The greater the risks to participants the more certain those approving the research must be that the risks will be minimised and managed appropriately and that the participants clearly understand the risks they are assuming. In accordance with the National Statement, risk is defined as the potential for harm or discomfort, and its evaluation involves an assessment of the likelihood and severity of the risk:

a. Lower risk research is that in which there is no risk of harm and the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not lower risk.
b. Higher risk research is that in which there is a risk of harm, including physical, psychological, social, cultural, economic and legal harm, and devaluation of a person's worth. Harms can be experienced individually or collectively (groups and communities).

(13) In accordance with the National Statement, certain types of research may require review by a Human Research Ethics Committee (HREC) regardless of the level of risk involved (unless conditions for exemption exist, see clauses 14-16 and clauses 25-27). This includes research involving:

a. genomics;
b. animal-to-human xenotransplantation;
c. access to a person's personal information (in medical research or personal health information) where a waiver of consent is required;
d. women who are pregnant and the human foetus;
e. people who are highly dependent on medical care who may be unable to give consent;
f. people with a cognitive impairment, an intellectual disability or a mental illness;
g. Aboriginal and Torres Strait Islander peoples;
h. people who may be involved in illegal activities;
i. health interventions; and
j. active concealment or planned deception.

Exemption from Review for Lower Risk Research using Existing Collections of Data or for Educational Purposes

(14) Lower risk research using existing collections of data may be exempt from ethics review if it meets all the following criteria:

a. The research meets the definition of lower risk; and
b. The research involves the use of existing collections of data or information about human beings from which all personal identifiers have been removed. The majority of existing collections of data that would be eligible for exemption are publicly available sources of aggregate information; and
c. Attempts to re-identify those with whom the data or information is associated is prohibited, and reasonable steps must be taken to prevent re-identification and/or non-authorised access or use; and
d. The original data collection and the proposed use of the data are consistent with the ethical principles outlined in the National Statement. Researchers must confirm that conditions of consent were appropriate and that the original consent covers the proposed research;
e. Permission from the data custodian is obtained prior to accessing the data and any conditions of access are observed.

(15) An application for exemption must be registered through MyResearch.

(16) Lower risk research conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only is exempt from ethics review.

Research Involving Lower Risk

(17) Research in which the only foreseeable risk is one of discomfort may be reviewed by a Lower Risk Panel. Applications will be directed to the researcher's relevant Panel and must be submitted through MyResearch.

Research Involving Higher Risk

(18) All research that involves higher risk requires review by an HREC. The University has established two NHMRC-registered HRECs, which operate in accordance with the National Statement. Applications for review must be submitted through MyResearch.

Ratification of Research Approved by an External Ethics Committee

(19) The University seeks to minimise the duplication of ethics review. In most instances a UQ researcher who has obtained approval from an external ethics committee is required only to register the approval, or seek ratification of it, at UQ. The University will typically recognise approvals from NHMRC-registered HRECs, delegated review bodies or equivalent international bodies. The external body provides the review, approval and monitoring of the research. It should be noted that research conducted overseas by researchers from Australian institutions must comply with the National Statement.

Ratification

(20) Projects involving any of the following require ratification of the external ethics approval:

a. UQ is the lead institution (Principal Investigator or Chief Investigator);
b. UQ is the sponsor;
c. UQ students undertaking research for their degree at the other institution (e.g., a hospital); and/or
d. UQ is a research site (e.g., testing and/or recruitment of participants at UQ).

(21) All modifications to the original approval, incident reports and annual reports that have been provided to the approving review body must also be submitted to UQ for review.

(22) Applications for ratification must be made through MyResearch. The lead UQ investigator is responsible for ensuring the project is submitted for ratification.

Registration

(23) All projects with external ethics approval that do not meet the conditions for ratification must be registered with UQ. The lead UQ investigator is responsible for ensuring the project is registered through MyResearch.

(24) Ratifications and registrations may be referred to other areas of the University for governance purposes.

Part B - Exemption for Quality Assurance and Evaluation Activities

(25) An activity of quality assurance is one where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation. An evaluation activity includes the systematic collection and analysis of information to judge the effectiveness, efficiency and/or appropriateness of an activity. Quality assurance and evaluation activities must be conducted in a way that is ethical, but in many situations, human research ethics review is not required. In accordance with the NHMRC guideline Ethical Considerations in Quality Assurance and Evaluation Activities, triggers for human research ethics review include:

a. where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations;
b. secondary use of data – where the data collected from the quality assurance or evaluation activity will be used for other purposes;
c. where data collected about the participant are beyond those which are collected routinely;
d. testing of innovative protocols or equipment;
e. comparison of cohorts;
f. randomisation, the use of control groups or placebos or targeted analysis of data involving minority/vulnerable groups; and
g. publication (including presentation) of the outputs of the quality assurance or evaluation activity outside the University.

(26) Where one or more of the above triggers apply, the activity may require review by an HREC or Lower Risk Panel. Research Ethics and Integrity may be contacted for assistance with determining the appropriate review pathway.

(27) In some circumstances an individual undertaking a quality assurance or evaluation activity may require a notice that attests to the activity being exempt from research ethics review. An application may be registered through MyResearch.

Part C - Complaints

Complaints About the Conduct of Research

(28) Complaints concerning the conduct of human research will be handled through the appropriate University process.

Concern relates to:	Process:
Participation in, or recruitment for, a research activity.	Report to the project lead or Research Ethics and Integrity.
Activities that have the potential to adversely affect participants, beyond that approved by the relevant ethics committee.	Report immediately to the project lead or Research Ethics and Integrity.

Concern relates to:	Process:
Activities that are not compliant with the approved protocol. Activities normally requiring ethics approval for which approval is not known to exist	Report to Research Ethics and Integrity. See also next section on concerns that raise the possibility of a breach.

(29) Complaints that raise the possibility of a breach of the University's Responsible Research Management Framework Policy will be handled as follows:

a. Staff and title holders: Managing Complaints about the Conduct of Research Procedure.
b. HDR candidates: Managing Complaints about the Conduct of Research - Higher Degree by Research Candidates Procedure.
c. Students other than HDR candidates: Student Integrity and Misconduct Policy.

(30) Projects that involve more than one institution and/or HREC will be handled in accordance with the agreement with that institution or, if no agreement exists, in negotiation with the external party.

Complaints About the Merit of an HREC or Lower Risk Review Process

(31) Complaints about the merit of a decision to provide ethics approval for an activity should be reported to Research Ethics and Integrity. The complaint will be provided to the relevant HREC or Lower Risk Panel Chairperson for consideration.

(32) Complaints from applicants concerning the HREC or Lower Risk Panel process should be progressed to the Director, Research Ethics and Integrity, who will review the process undertaken. The ultimate decision regarding the ethical acceptability of human research lies with the HREC or Lower Risk Panel and cannot be overridden by the University.

Section 4 - Roles, Responsibilities and Accountabilities

Deputy Vice-Chancellor (Research and Innovation)

(33) The Deputy Vice-Chancellor (Research and Innovation) or delegated officer is responsible for establishing and maintaining the operations, governance and resourcing of HRECs and Lower Risk Panels.

Review Bodies (HRECs and Lower Risk Panels)

(34) The primary responsibility of the University's HRECs and Lower Risk Panels is to ensure that all human research is conducted in compliance with the National Statement. These review bodies review and approve new applications and applications for amendments to existing approvals and provide advice to applicants on the ethical acceptability of the design and conduct of their research. The review bodies may also review concerns about activities related to an approved project and provide advice and recommendations to the University on issues related to human research ethics.

(35) UQ review bodies must operate in accordance with their terms of reference and meet reporting requirements per section 6 of this Procedure and the National Statement.

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Review Body Members

(36) In accordance with the National Statement, HREC and Lower Risk Panel members must:

a. be responsible for deciding whether, in their own judgement, a proposal submitted to the review body meets the requirements of the National Statement and is ethically acceptable. To fulfil that responsibility, each member of a review body should:
    i. become familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals;
    ii. for HREC members, prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences;
    iii. for Lower Risk Panel members, review applications in a timely manner, or indicate their unavailability when appropriate; and
    iv. attend continuing education or training programs in research ethics; and.
b. disclose any actual, potential or perceived conflict of interest, including any financial or other interest or affiliation that bears on any research coming before the review body.

Director, Research Ethics and Integrity

(37) The Director, Research Ethics and Integrity is responsible for receiving complaints concerning the processes of an HREC or Lower Risk Panel review that are not able to be resolved informally between the review body and the applicant. The Director will follow due process of complaints management and aim to resolve the complaint in a timely manner. Resolution may require consultation with other relevant parties.

Research Ethics and Integrity

(38) Research Ethics and Integrity is responsible for:

a. the management of the University's human research ethics review processes;
b. supporting the work of the University's review bodies; and
c. the provision of education, advice and support for researchers conducting human research.

Researchers

(39) In accordance with the National Statement, researchers must:

a. ensure and demonstrate that the proposed research has merit and reflects the ethical values of justice, beneficence and respect for humans;
b. obtain written ethics approval before commencing a project that involves human research, in accordance with this Procedure;
c. conduct a project in accordance with the conditions and requirements of the ethics approval, and cease the project if approval is suspended or withdrawn;
d. (for relevant health research) show that the research meets the requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, the World Health Organization International Clinical Trials Registry Platform and the TGA;
e. disclose all relevant interests and associations that may give rise to an actual, potential or perceived conflict of interest - this includes financial and non-financial interests and affiliations that bear on the research;
f. comply with relevant laws, regulations, disciplinary standards, ethics guidelines and University policies and procedures, including when conducting activities overseas;

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g. maintain records of the research in accordance with the approved protocol and the University's Information Management Policy; and
h. report to the UQ review bodies in accordance with section 6 of this Procedure.

Section 5 - Monitoring, Review and Assurance

(40) The Deputy Vice-Chancellor (Research and Innovation) is responsible for the development, compliance monitoring and review of this Procedure.

(41) The University will conduct reviews of the operation of its review bodies to ensure they are effective and consistent with the National Statement and University policies.

Section 6 - Recording and Reporting

(42) All meetings of review bodies are minuted, and records of all decisions maintained.

(43) UQ review bodies will:

a. maintain a record of all research proposals received and reviewed;
b. retain a copy of each research proposal and application for ethics approval, including any associated information and correspondence, that was approved; and
c. record decisions about approval, amendment or rejection of proposals in written or electronic form with reasons for those decisions linked to requirements of the National Statement.

(44) All researchers associated with the University must fulfil all reporting requirements, including submission of documents to MyResearch, Research Ethics and Integrity and the HREC or Lower Risk Panel as required.

Section 7 - Appendix

Resources

(45) Research Ethics and Integrity, Human Ethics website.

(46) Research Ethics and Integrity, Human Ethics – forms and resources web page.

Definitions

Term	Definition
MyResearch	The enterprise platform for the management and administration of research projects.
Participants	Any person who is the subject of the research.
Research	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.
Researcher	Any University staff member, student or title holder who conducts, or assists with the conduct of, research at, or on behalf of the University.
Review Body	UQ Human Research Ethics Committee (HREC) or Lower Risk Panel.
Staff	Continuing, fixed-term, research (contingent funded) and casual staff members.

Term	Definition
Student	A person enrolled as a student at the University or undertaking courses or programs at the University.
Title Holders	Visiting academics, academic title holders, industry fellows, emeritus professors, adjunct honorary title holders, and conjoint appointments.

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