

The University of Queensland Human Research Ethics Lower Risk Panel Terms of Reference April 2024



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| | Deputy Vice-Chancellor (Research and Innovation) |
| | The University of Queensland |



1. Introduction

Human Research is conducted with or about people, their data or tissue. To be ethically acceptable, human research must comply with the National Statement on Ethical Conduct in Human Research (2023) [National Statement] and demonstrate the values of research merit and integrity, justice, beneficence and respect. To make a judgement that a human research proposal meets the requirements of the National Statement, and is ethically acceptable, the University has established two Human Research Ethics Committees (HRECs). In accordance with the National Statement, which provides for review of lower-risk research outside of an HREC, the University has also established lower risk research review panels (hereafter Lower Risk Panels or just Panels) to evaluate research that is:

- Minimal risk: research involving no risk of harm or discomfort. There may be a foreseeable minor burden or inconvenience.
- Low risk: research involving 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 low risk. There may be a foreseeable burden or inconvenience.

As per the National Statement, research that is higher risk, and certain other categories of research, require review by an HREC. The UQ HRECs may also review and approve lower risk research applications. This may occur, for example, where there is a question about the level of risk or insufficient expertise available in a Lower Risk Panel.

This document provides the Terms of Reference for the University's Lower Risk Panels, consistent with section 5.1.29 of the National Statement.

2. Responsibilities

The objectives of the Lower Risk Panels are to:

- 2.1 Protect the mental and physical welfare, rights, dignity and safety of participants of research and minimise the risk of harm arising from research studies involving humans.
- 2.2 Promote ethical principles in human research by education of the academic community.
- 2.3 Review lower risk research in accordance with the National Statement.
- 2.4 Facilitate ethical human research through efficient and effective review processes of lower risk research as per UQ's Human Research Ethics Procedure.

The Lower Risk Panels functions on behalf of UQ to:

- 2.5 Provide oversight of lower risk human research projects in respect of their ethical acceptability where research is conducted at sites under the control of UQ and/or involves students, staff members or title holders of the University. Title holders refer to: visiting academics, academic title holders, industry fellows, emeritus professors, adjunct honorary title holders, and conjoint appointments.
- 2.6 Provide competent, timely ethics review and monitoring of human research projects for as long as they are active.



- 2.7 Ensure the compliance of human research projects with the principles of the National Statement and other relevant Acts and legislative requirements for that type of research, and grant, withhold, temporarily suspend, or withdraw ethics approval.
- 2.8 Protect the privacy and confidentiality of research participants by ensuring that researchers have considered the appropriate management of data and primary materials in accordance with UQ policy and relevant legislation.
- 2.9 Provide advice as to whether a proposed research activity should be reviewed by an HREC if it is considered to potentially be greater than low risk research or includes categories of research to be reviewed by an HREC.
- 2.10 Provide advice to the Deputy Vice-Chancellor (Research and Innovation) or delegate on strategies to promote awareness and understanding of the ethical conduct of lower risk human research within UQ and the broader community.

3. Accountability

- 3.1 The Lower Risk Panels are accountable to the Deputy Vice-Chancellor (Research and Innovation) or their delegate. Panels are established based on broad areas of research enquiry corresponding to UQ's Faculties and Institutes. Panels will be updated to reflect changes in the University governance structure and organisational units. A current list of panels is maintained on the UQ Human Research Ethics website.
- 3.2 The Lower Risk Panels operate under the guidance of, and are administratively supported by, Research Ethics and Integrity.
- 3.3 The Lower Risk Panel Chairperson brings to the attention of the Deputy Vice-Chancellor (Research and Innovation) or delegate issues of significant concern. In the first instance, Panel members should bring matters of concern to the relevant Chairperson.
- 3.4 Regular operational reports are made available by Research Ethics and Integrity to the relevant Panel Chairperson, Faculty Associate Dean Research and Institute Deputy Directors Research (as relevant) to allow for monitoring of workloads and planning.
- 3.5 The Lower Risk Panels report annually to the Deputy Vice-Chancellor (Research and Innovation). The report includes:
 - a summary of membership and membership changes;
 - the number of research projects reviewed, approved and rejected;
 - the number of annual and final reports received;
 - a summary of any suspensions or withdrawals of approval;
 - a summary of any appeals and complaints received;
 - monitoring procedures for research in progress and any issues identified by the Panel in undertaking its monitoring role;
 - general issues including advice on strategies to promote awareness of the ethical conduct of human research; and



• any resources required to assist the Panels in fulfilling their role.

An annual report will be prepared by Research Ethics and Integrity for consideration and approval by the Lower Risk Panel Chairpersons.

4. Membership

- 4.1 Panel membership comprises representatives from organisational units of the associated Faculty and Institute/s. As far as practicable, membership will reflect the diversity, including gender diversity, of the UQ community.
- 4.2 Efforts will be made to ensure that the number of members in each Panel ("Reviewers") is proportionate to the number of applications received from the members' associated organisational units (e.g., organisational units that conduct a high number of lower risk research projects will have more members on the associated Lower Risk Panel).
- 4.3 As a service role, there is an expectation that nominations to membership of Lower Risk Panels is supported by the member's supervisor and organisational unit head.
- 4.4 Members are required to:
 - 4.4.1 Become familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals.
 - 4.4.2 Review applications in accordance with the National Statement and any standard operating procedures.
 - 4.4.3 Provide informed opinions and feedback on the ethical acceptability of research proposals in a timely manner.
 - 4.4.4 Participate in review or monitoring of approved research if required.
 - 4.4.5 Attend continuing education or training programs in research ethics.
 - 4.4.6 Disclose any associations that may represent a conflict of interest.
- 4.5 On appointment, members are required to attend an induction session. New members are also encouraged to observe a meeting of an HREC.
- 4.6 New members may be partnered with the Panel Chairperson (or nominee) during the initial stages of their tenure to assist in their learning and development, depending on their experience and expertise.

5. Appointments

- 5.1 The Panel Chairperson is appointed by the Deputy Vice-Chancellor (Research and Innovation) or delegate, on recommendation from the relevant Faculty Associate Dean Research (ADR) and (where relevant) Institute Deputy Directors (Research), and the Director Research Ethics and Integrity.
- 5.2 Chairperson appointments will be for a term of 3 years, with extension possible. The letter of appointment includes the date of appointment, length of tenure and indemnity.
- 5.3 More than one Chairperson may be appointed according to workload demands of each Panel.



- 5.4 Deputy Chairpersons can be appointed as required based on workload requirements.
- 5.5 The Deputy Chairperson is appointed by the Director Research Ethics and Integrity or delegate, on recommendation of the Panel Chairperson.
- 5.6 Deputy Chairperson appointments will be for a term of 3 years, with extension possible.
- 5.7 Panel members are recruited by direct approach, nomination or by advertisement through an open and transparent selection process.
- 5.8 Panel members are appointed by the Director Research Ethics and Integrity or delegate on recommendation of the Panel Chairperson. Members are appointed based on their knowledge, qualities and experience. Prospective members may be asked to provide a copy of their curriculum vitae to the Chairperson and Research Ethics and Integrity.
- 5.9 The letter of appointment includes the date of appointment, length of tenure and indemnity.
- 5.10 Membership of the Lower Risk Panels, including member name and school/institute affiliation, may be made publicly available on UQ's web site.
- 5.11 All members are required to complete a conflict of interest declaration.
- 5.12 Members are appointed for a maximum initial period of 3 years. Subsequent reappointment will occur subject to Panel requirements.
- 5.13 Research Ethics and Integrity in conjunction with the relevant Panel Chairperson will continually review membership. New and renewed appointments will be made to allow for continuity, development of expertise within the panel, and regular input of fresh ideas and approaches.
- 5.14 Membership lapses if a member:
 - is unavailable to review lower risk applications without reasonable justification or in exceptional circumstances;
 - is late in reviewing applications without reasonable justification or in exceptional circumstances;
 - fails to attend training or undertake professional development activities related to their role as a Lower Risk Panel member as required by the Panel Chairperson or University.
- 5.15 The appointment of any member of a Lower Risk Panel may be terminated if the Chairperson is of the opinion that it is necessary for the proper and effective functioning of the Panel, or that the member has failed to carry out their duties as a Panel member.
- 5.16 The Director Research Ethics and Integrity or delegate notifies the member of a lapse or termination of membership in writing. The Head of the relevant organisational unit will also be notified.
- 5.17 Members seeking to resign or take a leave of absence for an extended period from a Lower Risk Panel are asked to provide at least four weeks written notice to the Chairperson and the Panel coordinator so that steps can be taken to fill the



- vacancy. Furthermore, Heads of the relevant organisational unit (School or Institute Deputy Director) should also be advised.
- 5.18 UQ provides indemnity for members of the Lower Risk Panel for liabilities that arise as a result of the member exercising their duties in good faith.

6. Role of Chairpersons and Deputy Chairpersons

Duties and responsibilities include, but are not limited to:

- 6.1 Providing leadership and impartial guidance to the Lower Risk Panel Reviewers and the UQ research community in relation to the responsible and ethical conduct of human research.
- 6.2 Fostering appropriate education and training in relation to human research ethics to Lower Risk Panel Reviewers, researchers and students.
- 6.3 Liaising with the Panel coordinator regarding appropriate procedures.
- 6.4 Promoting good communication between Reviewers, researchers and the University.
- 6.5 Contributing to the development and/or review of UQ policies, procedures and operational guidelines related to human research ethics, including through membership of the Human Research Ethics Advisory Group (HREAG).
- 6.6 Attending to routine and arising matters, including:
 - reviewing applications and amendments, reports and complaints about the conduct of approved research in a timely manner;
 - moderating reviewer assessment;
 - assisting with recruitment and training of Panel Reviewers;
 - representing UQ in human research ethics forums;
 - supporting the monitoring of compliance and safety in human research.
- 6.7 The Panel Deputy Chairperson can substitute for the Chairperson in their absence or when required due to workload or a conflict of interest.

7. Operations

7.1 Procedures

- 7.1.1 The Lower Risk Panel conducts its business in accordance with the UQ <u>Human Research Ethics Procedure</u>, this Terms of Reference and any Standard Operating Procedures, noting National Statement Guidance 5.1.12 5.1.14.
- 7.1.2 The Lower Risk Panel Terms of Reference are made publicly available on UQ's web site.

7.2 Review of Applications

7.2.1 Applications are submitted and reviewed through the MyResearch Ethics portal. The review process is coordinated by Research Ethics and Integrity.



- Applications are distributed based on reviewer availability and area of expertise.
- 7.2.2 Generally, two reviewers will be assigned to each lower risk application. The reviewers independently evaluate the application and provide their recommendation. The reviewers may contact each other to discuss the application if they determine this would be of assistance. The Panel coordinator may also encourage the reviewers to discuss any differences of opinion when these arise.
- 7.2.3 The Panel Chairperson can be asked to provide further advice should there be conflicting review outcomes that cannot be resolved in accordance with 7.2.2. or where it is otherwise prudent to do so.
- 7.2.4 Panel Chairpersons can meet with reviewers and researchers to discuss issues arising from a review.
- 7.2.5 Reviewers are requested to return reviews within five (5) working days of receipt of applications for review. Where this cannot be achieved, reviewers should promptly advise Research Ethics and Integrity.
- 7.2.6 Reviewer feedback on applications will be consolidated by Research Ethics and Integrity and may be edited for consistency and clarity before being provided to an applicant.
- 7.2.7 Applications for amendments to an existing approval may be reviewed by a Panel Chairperson, Reviewer and/or coordinator. Panel Chairpersons, in consultation with Research Ethics and Integrity, will determine the best method for reviewing amendments depending on workload and availability of personnel.
- 7.2.8 When required, review of an application can be assigned to another Panel or an HREC by the Chairperson or Research Ethics and Integrity.

7.3 **Declaration of interests**

- 7.3.1 Prior to undertaking review of an application, Reviewers must declare associations that may give rise to any actual, potential or perceived conflict of interest they have in relation to the ethics application. Should a member identify a conflict of interest at a later time during review of an application, this must be declared at that time.
- 7.3.2 If there is a conflict of interest that cannot be appropriately managed the application will be assigned to an alternate Reviewer.

7.4 Confidentiality

- 7.4.1 Applications, supporting documentation and related correspondence and Panel deliberations are treated confidentially.
- 7.4.2 All lower risk human research ethics applications are treated as confidential and will not be shared for purposes other than undertaking or assessing the ethics review, unless agreed to by the applicant or required by an authorised process or officer of the University (e.g., an application may be shared for the purpose of an investigation into the conduct of the research in question).
- 7.4.3 Reviewers should access applications through My Research and ensure that downloaded copies are permanently deleted after review.



7.5 **Decision making**

- 7.5.1 Reviewers can recommend that the application to undertake research is:
 - approved as being ethically acceptable;
 - returned to the applicant for modification or to obtain additional information;
 - rejected;
 - greater than low risk.
- 7.5.2 If consensus in review cannot be reached, the Lower Risk Panel Chairperson will determine how the review will proceed.

7.6 Records

- 7.6.1 Research Ethics and Integrity will ensure all reviewer records are maintained.
- 7.6.2 Research Ethics and Integrity will prepare and maintain an official file for each application received, including a copy of the application and any other relevant correspondence between the applicant, reviewers and Research Ethics and Integrity.
- 7.6.3 Research Ethics and Integrity will also maintain a database of all the applications received and reviewed in accordance with the National Statement.
- 7.6.4 Records will be held as per University requirements and under the relevant State Retention and Disposal schedule.

7.7 Monitoring research projects

- 7.7.1 The Chairperson and Lower Risk Panels monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.
- 7.7.2 The Lower Risk Panel Chairperson has the discretion to adopt other appropriate mechanisms for monitoring research, including:
 - discussion of relevant aspects of the project with investigators, at any time;
 - audits of compliance with the approved protocol;
 - random inspection of research sites, data, or consent documentation;
 - interview with research participants or other forms of feedback from them:
 - request and review reports from independent agencies or monitors.

8. Appeals and Complaints

8.1 Action regarding lower risk rejection

Where the review panel has rejected an application, the applicant may lodge an appeal with the Chairperson (via Research Ethics and Integrity) specifying the grounds of the appeal in writing. The Chairperson will provide a response in writing.

An applicant may also submit a new application taking into consideration any feedback received on their rejected application.

8.2 Appeals on the basis of process

If an applicant considers that the Lower Risk Panel has failed to follow due process, and the matter cannot be resolved through discussion with the Chairperson, they may lodge a complaint with the Director, Research Ethics and Integrity, in accordance with the UQ Human Research Ethics Procedure.

8.3 Complaints about the conduct of Lower Risk Panel members

Complaints about the conduct of a Lower Risk Panel member are managed by the Director Research Ethics and Integrity or delegate who, where appropriate, informs the Chairperson of the complaint. Complaints about the conduct of the Panel Chairperson are managed by the Deputy Vice-Chancellor (Research and Innovation) or delegate.

8.4 Complaints about the conduct of an approved research project

Complaints about the conduct of an approved research project are managed by the relevant Chairperson, with assistance from Research Ethics and Integrity. Complaints that represent a potential breach of the Australian Code for the Responsible Conduct of Research are managed in accordance with UQ's complaint handling procedures (see the UQ Human Research Ethics Procedure for details).

9. Review of Terms of Reference and Termination

- 9.1 These Terms of Reference will be reviewed every three years.
- 9.2 Where the Panel is to be merged, closed or has ceased to function, UQ will notify relevant stakeholders and amend the Terms of Reference, as required.

9.3 Revision history

| Version | Approval date | Effective date | Extent of revision |
|---------|--|----------------|--|
| | Draft version 8.0 – not approved | | First release for newly formed 'Low and Negligible Risk' Panels after major restructure of UQ's human research ethics review processes. Document remained in draft with no record of approval. |
| 2.0 | 29 April 2024 | • | Significant revisions to reflect changes to National Statement and UQ's operational environment. |

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