HUMAN RESEARCH ETHICS APPROVALS PROCEDURE

CONTENTS

1 PURPOSE

1.1 This procedure outlines how CQUniversity will manage research projects involving people or their data or tissue.

2 SCOPE

2.1 This procedure applies to members of the CQUniversity Human Research Ethics Committee, and CQUniversity employees and students who conduct research with or about people, or their data or tissue.

3 PROCEDURE

3.1 Projects involving people, and their data or tissue, must receive ethical approval and be managed in accordance with the National Statement on Ethical Conduct in Human Research.

3.2 The University's Human Research Ethics Committee is responsible for providing ethical approval and managing approved research projects involving people, and ensuring compliance with the National Statement on Ethical Conduct in Human Research. Details about the Committee's operations including membership requirements, quorum and meeting observers are available in the Human Research Ethics Committee Terms of Reference.

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Applications

Submitting applications

3.3 Approval from the Human Research Ethics Committee must be sought before any research is undertaken.

3.4 Applications for ethical clearance will be submitted using the University's online ethics application system. Applications which are deemed as low risk or negligible risk research will be assessed outside of the Committee. Those which do not meet the criteria for low risk will be referred to the next meeting of the full Committee for consideration.

3.5 The Committee will only consider applications from persons affiliated with the University and will not charge fees for its considerations.

3.6 Applications received after the application submission date will not be accepted and will be included on the agenda for the next scheduled meeting.

3.7 Applications from undergraduate or postgraduate coursework students will be submitted using a suite of forms provided by the Ethics Office, and will be considered outside of the Committee by the Ethics Officers, Chair and selected low risk reviewers.

3.8 Regardless of the manner of consideration, submission of an application does not guarantee approval. The outcome of the review, whether by the full committee or any other mechanism may include a request for further information or clarification which will be provided in the form of a table responses, and that researchers will be required to provide a point-by-point response to each request in the table.

Low risk project decisions

3.9 Applications which meet the low risk eligibility criteria will be considered and recommended outside of the Committee by two selected low risk reviewers and the Ethics Officers, to the Committee Chair for approval. Initial consideration to applications will be completed no later than three weeks after receipt of an application, and will be completed no later than eight weeks after its receipt.

Committee decisions

3.10 The Committee will aim to provide initial consideration to applications no later than four weeks after receipt of an application, and complete its consideration no later than eight weeks after its receipt.

3.11 The Committee may request the principal researcher/s of an application to be available during Committee discussions on that application.

3.12 The Committee may only approve applications which:

- conform to the requirements of the National Statement on Ethical Conduct in Human Research, and
- conform to any other relevant legislation.

3.13 The Committee will strive to reach decisions by general agreement or consensus.

3.14 When a generally agreed or consensus decision cannot be reached by the Committee, the Committee will defer its consideration to a further meeting at which advice from experts and/or the proposer/s of the research may be provided to assist in the Committee's consideration.

3.15 If the Committee is unable to reach general agreement in making a decision following any further consideration and/or advice the Committee members may vote on the matter.

3.16 In the event of a vote, assent by two-thirds of the members will decide the matter.

3.17 Once the minutes have been confirmed by the Chair, the Secretary will advise the principal researcher/s in writing of the Committee's decision within five working days.

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3.18 The following condition of approval for any application will be included in the formal advice to the principal researcher/s:

"It is a condition of approval of this research project that you report immediately anything which may warrant review of ethical approval of the research protocol, including:

- *serious or unexpected adverse effects on participant/s*
- *proposed changes in the protocol, and*
- *unforeseen events that might affect continued ethical acceptability of the project.*

A written report detailing the adverse occurrence or unforeseen event must be submitted to the Committee Chair within one working day after the event."

Applications previously approved by another human research ethics committee

3.19 If an applicant has received approval from another Human Research Ethics Committee registered with the National Health and Medical Research Council, the applicant may provide the Committee with a copy of the application (including supporting documentation) and approval letter/certificate for consideration/approval.

3.20 Previously approved applications with potential for physical or psychological harm may not necessarily receive automatic approval. This includes drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

3.21 The Committee retains the right to apply additional conditions of approval.

Modifications

Applications

3.22 Where a project previously approved by the Committee requires modifications, the Committee will provide a proforma detailing the format and requirements for presentation for applications to modify an approved project.

3.23 Applications for minor modifications may be assessed by the Chair on behalf of the Committee. If the requested modification is only to extend the end date of an approved project, approval may be sub-delegated to the Secretary.

3.24 The Chair will refer applications requesting major modifications to be assessed by the Committee at the next scheduled meeting.

Committee decisions

3.25 The Committee will review and decide on modification applications in the same way as a new application. Refer to the Committee Decisions section under Applications for information on how the Committee will determine this decision.

Chair decisions

3.26 The Committee has delegated the Committee Chair the authority to:

- approve applications for minor modifications. This may be sub-delegated to the Secretary if the requested modification is only to extend the end date of a proposed project
- carry out random unannounced inspections of approved research projects, particularly in response to complaints or concerns raised by participants or members of the general public
- withdraw and restore ethical approval, and make recommendations to the Vice-President (Research) for projects with adverse occurrences or unforeseen events. Refer to the adverse occurrences and unforeseen events section for further information.
- withdraw and restore ethical approval, and make recommendations to the Vice-President (Research) for non-compliant projects. Refer to the non-compliance section for further information.

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3.27 Any decision made by the Chair will be reported to and reviewed by the whole Committee for formal ratification at its next scheduled meeting.

3.28 Where a Committee member is aggrieved by a decision of the Chair, they should follow the Human Research Ethics Committee Grievance Procedure.

Monitoring projects

3.29 The University is responsible for monitoring research conducted by its researchers (as per clause 5.5.1 of the National Statement on Ethical Conduct in Human Research). Mechanisms can include:

- reports from researchers
- reports from independent agencies (such as a data and safety monitoring board)
- review of adverse event reports
- random inspections of research sites, data or consent documentation, or
- interviews with research participants or other forms of feedback from them.

3.30 As a condition of a project being approved, researchers must submit:

- annual reports for projects of greater than 12 months duration, due on the anniversary date of approval, and
- final reports one month after the completion date for all projects.

3.31 The Committee will prepare a proforma detailing the format and requirements for presentation of annual and final reports and will stipulate that the reports must address matters including:

- progress to date or outcome in the case of completed research
- maintenance and security of records
- compliance with the approved research protocol, and
- compliance with any conditions of approval (as per clause 5.5.5 of the National Statement on Ethical Conduct in Human Research).

3.32 The Committee may also determine if additional monitoring is required. The Committee will record in the minutes the frequency and type of monitoring required according to the degree of risk to participants in the research project and the persons responsible for the monitoring.

3.33 Where the Chief Investigator leaves the University prior to the completion of the project, they must complete a final report, or nominate an alternative researcher to assume responsibility as Chief Investigator.

3.34 Where a student researcher withdraws from their program (research higher degree (RHD) candidates), or unit of study (for coursework students) the student must complete a final report, but will not have the opportunity to nominate an alternative Chief Investigator.

3.35 All reports will be considered by the Committee at its monthly meetings. Reports with adverse events will be listed separately on the agenda, together with any actions taken for consideration at the meeting.

3.36 The Secretary is responsible for ensuring monitoring of projects occurs as required and that monitoring reports are received.

3.37 Non-receipt of reports will be followed up, with escalation to the Deputy Dean Research, the Dean, School of Graduate Research for RHD candidate projects, and to the Vice-President (Research) as appropriate.

Adverse or unforeseen events

3.38 It is a condition of approval for projects that anything that may warrant review of ethical approval of the research protocol be reported immediately.

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3.39 A written report detailing any adverse occurrences or unforeseen events must be submitted within one working day after the event. The Secretary will forward reports of adverse occurrences to the Chair no later than one working day of receipt.

3.40 The Chair will consider the report and determine the appropriate action. The Chair will have delegated authority to:

- consult with any other members of the Committee and any other parties to seek advice and assistance in addressing matters arising from any report of adverse occurrence or unforeseen event
- withdraw ethical approval for an approved project and advise the principal researcher/s, supervisor (if applicable), the Vice-President (Research), Secretary and any other formal parties to the approved project to this effect in writing
- recommend to the Vice-President (Research) that data collection under an approved project be suspended, discontinued or other necessary steps be taken
- restore ethical approval for a suspended project and advise the principal researcher/s, supervisor (if applicable) the Vice-President (Research), Secretary and any other formal parties to the research project to this effect in writing, if satisfied that appropriate action has been taken to ensure no further adverse occurrence or event of similar kind, and
- refer instances of misconduct by employees to the Vice-President (Research) for review and/or action in accordance with the Code of Conduct for Research
- refer instances of misconduct by RHD candidates to the Dean, School of Graduate Research for review and/or action in accordance with the Research Higher Degree Integrity Policy and Procedure
- refer instances of misconduct by coursework students to the Deputy Dean Learning and Teaching for review and/or action in accordance with the Student Academic Integrity Policy and Procedure.

3.41 The Chair will report on any matters involving adverse occurrences to the Committee at its next scheduled meeting for formal ratification of any withdrawal or restoration of approval.

Complaints

3.42 Any complaints regarding the use of humans in research will be managed in accordance with the Human Research Ethics Committee Grievance Procedure.

3.43 The Secretary will maintain a register of complaints and resolutions.

3.44 Complaints, including their resolutions, will be included in the Committee's Annual Reports to the Research Committee and the National Health and Medical Research Council.

Non-compliance breaches

Non-compliance with the National Statement on Ethical Conduct in Human Research

3.45 Where inspections detect activities of non-compliance with the National Statement on Ethical Conduct in Human Research or approval conditions, the Secretary or monitoring committee member/s must report immediately to the Committee Chair.

3.46 The Chair has the delegation of authority to:

- consult with any other members of the Committee and any other parties to seek advice and assistance in addressing matters arising from any report of non-compliance
- withdraw ethical approval for a research project/teaching activity and advise the researcher/s or student/s, the Vice-President (Research) and any other formal parties to the project to this effect in writing
- recommend to the Vice-President (Research) that a project/activity be suspended, discontinued or that other necessary steps be taken, and
- restore ethical approval for a research project/teaching activity and advise the researcher/s or student/s, the Vice-President (Research) and any other formal parties to the project to this effect in writing, if satisfied that appropriate action has been taken to ensure no further adverse occurrence or similar event.

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3.47 Where the Chair or the Committee determines a project is not being conducted or cannot be conducted in accordance with the approved protocol, the project will be referred as outlined below:

- projects undertaken by employees will be referred to the Vice-President (Research) for review and/or action in accordance with the Code of Conduct for Research
- projects undertaken by RHD candidates will be referred to the Dean of the School of Graduate Research for review and/or action in accordance with the Student Research Misconduct Policy and Procedure
- projects undertaken by coursework students will be referred to the Deputy Dean Learning and Teaching for review and/or action in accordance with the Student Academic Integrity Policy and Procedure.

3.48 Any valid breach will be included in the Committee's Annual Reports to the Research Committee and the National Health and Medical Research Council.

Non-compliance with the Australian Code of for the Responsible Conduct of Research

3.49 Where there are concerns that a research project is breaching the Australian Code for the Responsible Conduct of Research, the Vice-President (Research) will determine whether the matter will proceed to a Preliminary Assessment. Refer to the Code of Conduct for Research for further information.

Discontinuation of an approved project

Committee advising the principal researcher/s

3.50 Where the Committee determines a project is not being conducted or cannot be conducted in accordance with the approved conditions, and that the welfare and rights of the participants are not or will not be protected, the Committee will withdraw its ethical approval.

3.51 The Committee will formally advise the principal researcher/s, supervisor (if applicable), Vice-President (Research) of any withdrawal of ethical approval and recommend that the project be discontinued, suspended or that specified steps be taken to allow the project to continue.

Principal researcher/s advising the committee

3.52 As a condition of approval, the principal researcher/s must report of the project discontinuation within five working days to the Committee.

Confidentiality

3.53 Applications submitted for ethics approval will remain confidential to the Committee and its Secretary.

3.54 Each project file with associated documents will be accorded high security status and be accessible only by Committee members and the Secretary.

3.55 Reports and agenda papers will remain confidential to the Committee, the Secretary and Research Committee except as required by law, and where specified extracts from reports or documents are authorised by the Committee to be conveyed to:

- an applicant seeking ethical approval
- a research funding body
- an expert adviser to the Human Research Ethics Committee, and
- the Vice-President (Research) in the event of a complaint concerning a research project or irreconcilable difference with the Committee.

4 RESPONSIBILITIES

Compliance, monitoring and review

4.1 The Vice-President (Research), the Committee and the Research Division are responsible for implementing, monitoring, reviewing and ensuring compliance with this procedure.

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Reporting

4.2 The Committee will report annually to the Research Committee which will include:

- numbers and types of applications assessed and approved or rejected
- breaches of the National Statement on Ethical Conduct in Human Research and University policy documents
- compliance reporting
- monitoring
- training and education
- complaints
- membership and meeting attendance
- administrative or other difficulties being experienced, and
- any matters that may affect the institution's ability to maintain compliance with the National Statement on Ethical Conduct in Human Research and if necessary, the provision.

Records management

4.3 Employees must manage records in accordance with the Records Management Policy and Procedure. This includes retaining these records in a recognised University recordkeeping system.

4.4 University records must be retained for the minimum periods specified in the relevant Retention and Disposal Schedule. Before disposing of any records, approval must be sought from the Records and Privacy Team (email records@cqu.edu.au).

4.5 The Secretary will keep the following records for each application submitted for ethics approval:

- name of the principal researcher/s
- name of all other researchers
- title of project
- associated documentation with the application including:
  - information sheets
  - consent forms
  - research instruments
  - letters of approval or
  - relevant correspondence
- assessment type
- Initial and current assessment status and with date
- terms and conditions if any of approval of any protocol
- whether the opinion of another Human Research Ethics Committee was considered
- action taken by the Committee to monitor the conduct of the research
- relevance (if any) of the Guidelines under Section 95 of the *Privacy Act 1988*
- applications for modifications and assessment details, and
- reports (both annual and final).

4.6 For multi-centre applications the following will also be on record:

- details of other centres/institutions involved

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- approval status of the study at each centre/institution, and
- details of any amendments required at other centres.

5 DEFINITIONS

5.1 Terms not defined in this document may be in the University glossary.

Terms and definitions

Low risk: research in which the only foreseeable risk is one of discomfort (as defined in the National Statement on Ethical Conduct in Human Research)

Negligible risk research: research where there is no foreseeable risk of harm or discomfort, and any foreseeable risk or no more than inconvenience (as defined in the National Statement on Ethical Conduct in Human Research)

6 RELATED LEGISLATION AND DOCUMENTS

Australian Code for the Responsible Conduct of Research

Code of Conduct for Research

Ethical Conduct in Research with Aboriginal and Torres Strait Islander People and communities

Guidelines under Section 95 of the *Privacy Act 1988*

Human Research Ethics Committee Grievance Procedure

Human Research Ethics Committee Terms of Reference

Human Rights Act 2019 (Qld)

Keeping Research on Track II

National Statement on Ethical Conduct in Human Research

Research Higher Degree Integrity Policy and Procedure

Student Academic Integrity Policy and Procedure

7 FEEDBACK

7.1 Feedback about this document can be emailed to policy@cqu.edu.au.

8 APPROVAL AND REVIEW DETAILS

Approval and Review	Details
Approval Authority	Academic Board
Delegated Approval Authority	Research Committee
Advisory Committee	Human Research Ethics Committee
Required Consultation	N/A
Administrator	Vice-President (Research)
Next Review Date	24/06/2024

Approval and Amendment History	Details
Original Approval Authority and Date	Research Committee 24/06/2021
Amendment Authority and Date	Vice-President (Research) 20/07/2021
Notes	This document consolidated and replaced the Human Research Ethics Committee Operating Procedure and the Human Research Ethics Committee Monitoring Policy and Procedure (approved 24/06/2021).

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