

HUMAN RESEARCH ETHICS COMMITTEE OPERATING PROCEDURE



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1 PURPOSE

- 1.1 This procedure has been developed in accordance with the requirements of the [National Statement on Ethical Conduct in Human Research 2007](#).

2 SCOPE

- 2.1 This procedure applies to CQUniversity staff and students who conduct research with or about people, or their data or tissue.

3 PROCEDURE

Meeting frequency

- 3.1 The Human Research Committee will meet once each month, or as required.

Preparation of agendas, reports and associated documentation

- 3.2 The Research Division will appoint a Secretary of the Committee, who will consult with the Chair in the preparation of reports and agenda for the Committee and any sub-committees or working parties.
- 3.3 The Secretary will be responsible for final preparation, distribution and record-keeping of all reports, agenda and associated agenda documents.
- 3.4 Members may request, through the Chair or Secretary, that an item be placed on the agenda for any meeting.
- 3.5 Reports of meeting will be drafted within two working days of the meeting and draft report confirmed by the Chair within two working days of receipt.

Meetings – distribution of papers

- 3.6 Papers for meetings of the Committee will be despatched by the Secretary to members, to an address nominated by each member, at least five working days in advance of any scheduled meeting.
- 3.7 Papers for any matter to be considered by any sub-committee of the Committee will be despatched by the Secretary to members, to an address nominated by each member, at least five working days in advance of any scheduled meeting.

Low risk applications – distribution of papers

- 3.8 Applications for low risk projects will be despatched by email by the Secretary to two Committee members within two days of receipt.
- 3.9 The Committee will prepare a pro-forma for use by researchers applying for ethical clearance under the low risk process detailing the format and requirements for presentation of applications.
- 3.10 Hand written applications will not be accepted.
- 3.11 Requests for expedited review must include the standard application pro-forma including supporting documentation and be accompanied by a justification for the request.

Presentation of applications

- 3.12 Applications which do not meet the criteria for low risk will be referred to the next meeting of the full Committee for consideration.

Presentation of applications for modifications

- 3.13 The Committee will prepare for use a pro-forma detailing the format and requirements for presentation for applications to modify an approved project.

Timely consideration and review of research protocols

- 3.14 Where practicable, meetings of the Committee will be scheduled to enable timely consideration of research applications in relation to closing dates for applications for research grants from the:
- Australian Research Council
 - National Health and Medical Research Council, and
 - following the award of any Internal Research Grant which is subject to ethical approval.

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

Meetings

- 3.16 The Committee will aim to have given initial consideration to any application by no later than four weeks after receipt of an application and to have completed its consideration by no later than eight weeks after its receipt.

Low risk application review

- 3.17 Committee members assessing an application will aim to have given initial consideration to any application by no later than five working days after receipt of an application and to have completed its ratification by no later than four weeks after its receipt.

Minor applications for modification

- 3.18 Minor applications for modifications to an approved project may be assessed by the Chair on behalf of the Committee. If the modification seeks only to extend the end date of an approved project, approval may be delegated to the Secretary.
- 3.19 The Secretary will despatch the application to the Chair no later than two working days of receipt.
- 3.20 The Chair will assess the application no later than five working days of receipt of the application.

Major applications for modification

- 3.21 Major applications for modifications to an approved project will be assessed by the whole Committee at the next scheduled meeting.

Methods of decision making for meetings

- 3.22 The Committee may request the Principal Researcher/s for an application or approved project to be available at the time of the meeting for the agenda item during which that application or approved project is to be the subject of a decision to be made by the Committee.
- 3.23 The Committee will strive to reach decisions by general agreement or consensus.
- 3.24 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.
- 3.25 When a generally agreed or consensus decision cannot be reached by the Committee concerning an application, 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.
- 3.26 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.
- 3.27 In the event of a vote on a motion/recommendation, assent by two-thirds of the members will decide the matter.
- 3.28 Where a Committee member is aggrieved by a decision of the Committee he/she should follow the procedures provided in the document, [Human Research Ethics Committee Grievances Procedure](#).

Methods of decision making – low risk applications

- 3.29 Requests for ethical clearance for low risk projects will be despatched to two Committee members for consideration no later than one working day of receipt.
- 3.30 The two members will aim to provide their recommendation by no later than five working days of receipt.
- 3.31 Committee members unable to provide assistance with this process will notify the Secretary immediately.
- 3.32 The Secretary will collate and forward Committee members' assessment to the Chair by no later than one working day following receipt of both assessments.
- 3.33 The Chair will determine the assessment of application on behalf of the Executive Committee taking into consideration each member's response.
- 3.34 Where one or both reviewers determine that the project does not meet the eligibility criteria for low risk research, the Secretary will consult with the Chair and Deputy Chair. Where the Chair and Deputy Chair agree that the project cannot be considered as low risk, the principal researcher will be advised that the application will be considered at the next scheduled meeting of the full Committee. Where the Chair and Deputy Chair consider that with some amendment, the project COULD meet the criteria for low risk, the researcher will be apprised of the required amendments. In cases where the Chair and Deputy Chair are not in agreement, the final decision rests with the Chair.
- 3.35 The Chair 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.
- 3.36 Any decision made by the Chair will be reported to and reviewed by the whole Committee for formal ratification at its next scheduled meeting. The Committee will be provided with a summary of the applications approved, and will be invited to advise the secretary of any items requiring discussion, so that full documentation can be brought to the meeting.
- 3.37 Where a Committee member is aggrieved by a decision of the Chair he/she should follow the procedures provided in the document, [Human Research Ethics Committee Grievances Procedure](#).

Methods of decision making – applications for modification

- 3.38 Any decision made by the Chair will be reported to and reviewed by the whole Committee for formal ratification at its next scheduled meeting. The Committee will be provided with a summary of the modifications approved, and will be invited to advise the Secretary of any items requiring discussion, so that full documentation can be brought to the meeting

Methods of decision making – applications previously approved by another human research ethics committee

- 3.39 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.
- 3.40 Projects 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.
- 3.41 The Committee retains the right to apply additional conditions of approval.

Conflict of interest

- 3.42 In the event of a conflict of interest, Committee members are required to state any conflict of interest for each meeting and then leave the room when decisions relating to approval and conditions of the application are made. This is necessary to ensure equity for all applicants.
- 3.43 Any conflict of interest will be recorded in the meeting minutes.

Prompt notification of decisions - meeting

- 3.44 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.

Prompt notification of decisions - low risk applications

- 3.45 From the receipt of the application, the Secretary will advise the Principal Researcher/s in writing of the Chair's decision within 15 working days.
- 3.46 The Principal Researcher/s will be advised in writing that the executive approval is subject to ratification by the whole Committee at the next scheduled meeting and additional conditions may be imposed.

Minor applications for modification

- 3.47 From the receipt of the application, the Secretary will advise the Principal Researcher/s in writing of the Chair's decision within 10 working days.

Major applications for modification

- 3.48 Once the report has been confirmed by the Chair, the Secretary will advise the Principal Researcher/s in writing of the Committee's decision within five working days.

Monitoring of research projects

- 3.49 As part of its decision making of each application, the Committee will determine if additional monitoring is required and will resolve the frequency and type of monitoring required according to the degree of risk to participants in the research project, the persons responsible for the monitoring and will record these decisions.
- 3.50 As a condition of ethics approval, all approved projects must submit annual and final reports.
- 3.51 The Committee will prepare a pro-forma 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
 - compliance with any conditions of approval.
- 3.52 The Secretary will be responsible for ensuring that the monitoring occurs as required and that monitoring reports are received.
- 3.53 Where the Chief Investigator leaves the University prior to the completion of the project, he/she will be issued with a request to complete a final report, or to nominate an alternative researcher to assume responsibility as Chief Investigator.
- 3.54 In the case of student researcher who withdraws from their program, the student will be issued with a request to complete a final report, but will not have the opportunity to nominate an alternative Chief Investigator.

- 3.55 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.
- 3.56 Non receipt of reports will initially be followed up with the researchers, with escalation to the Deputy Dean of Research for the respective School, and to Deputy Vice-Chancellor (Research) as appropriate.

Reporting of adverse occurrences

- 3.57 The Committee will ensure that the following condition of approval for any application is 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.”

- 3.58 The Secretary will forward reports of adverse occurrences to the Chair no later than one working day of receipt.
- 3.59 The Chair will consider the report and will 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 approval for an approved project and advise the Principal Researcher/s, supervisor (if applicable), the Deputy Vice-Chancellor (Research), Secretary and any other formal parties to the approved project to this effect in writing
 - recommend to the Deputy Vice-Chancellor (Research) that an approved project be suspended, discontinued or other necessary steps be taken
 - restore approval for a suspended project and advise the Principal Researcher/s, supervisor (if applicable) the Deputy Vice-Chancellor (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
- 3.60 The Chair will report on any matters involving adverse occurrences to the whole Committee at its next scheduled meeting for formal ratification of any withdrawal of approval or restoration of approval.

Receiving complaints

- 3.61 The Committee will follow the [Human Research Ethics Committee Grievance Procedure](#).
- 3.62 The Chair may consult with any other member of the Committee to seek advice and assistance in attempting to resolve any complaint or address any concern.
- 3.63 The Chair may refer the complaint or concern to the Committee for resolution.
- 3.64 In the event the Committee cannot resolve a complaint or concern the matter must be referred to the Deputy Vice-Chancellor (Research) in accordance with sections 11-15 of the University's [Code of Conduct for Research](#).
- 3.65 The Secretary will maintain a register of complaints and resolutions.
- 3.66 All complaints will be included in the National Health and Medical Research Council Australian Human Ethics Committee Annual Report for the Committee.

Non-compliance with the national statement on ethical conduct in human research and/or university policy

- 3.67 In the event that an approved project is in breach of the [National Statement on Ethical Conduct in Human Research](#), relevant legislation or University policy, the Committee will suspend approval immediately, investigate the project and ensure that appropriate action is taken. The Committee will follow the [Student Research Misconduct Policy and Procedure](#) and/or the [Human Research Ethics Committee Grievance Procedure](#) to resolve any breach.
- 3.68 Any valid breach will be included in the National Health and Medical Research Council Australian Human Ethics Committee Annual Report for the Committee and the Committee Annual Report to the Institution.

Advising of the discontinuation of an approved project:

The committee advising the principal researcher/s

- 3.69 In the event that the Committee has determined that an approved project is not being conducted or cannot be conducted in accordance with the approved project and that the welfare and rights of the participants are not or will not be protected, the Committee will withdraw its approval.
- 3.70 The Committee will formally advise the Principal Researcher/s, supervisor (if applicable), Deputy Vice-Chancellor (Research) and the Secretary of any withdrawal of approval and recommend to the Deputy Vice-Chancellor (Research) that the project be discontinued, suspended or that specified steps be taken to allow the project to continue.

Principal researcher/s advising the committee

- 3.71 As a condition of approval, the Principal Researcher/s must report of the project discontinuation within five working days to the Committee.
- 3.72 Fees: the Committee will only consider applications from persons affiliated with CQUniversity and will charge no fees for its considerations.

Confidentiality of the content of applications and committee proceedings

- 3.73 Applications submitted for ethics approval will remain confidential to the Committee and its Secretary.
- 3.74 Each project file with associated documents will be accorded high security status and be accessible only by Committee members and the Secretary.
- 3.75 Reports, agenda and committee papers of the Committee 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 Deputy Vice-Chancellor (Research) in the event of a complaint concerning a research project or a grievance or an irreconcilable difference with the Committee.

4 RESPONSIBILITIES

Compliance, monitoring and review

- 4.1 The Human Research Ethics Committee and the Research Division is responsible for ensuring that this policy and its corresponding procedures are complied with.

Reporting

- 4.2 The Committee will report annually to the Research Committee and the report 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
 - 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](#) and if necessary the provision.

Records management

- 4.3 Staff must maintain all records relevant to administering this procedure in a recognised University recordkeeping system.
- 4.4 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
 - 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 Human Research Ethics 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.
- 4.5 For multi-centre applications the following will also be on record:
- details of other centres/institutions involved
 - approval status of the study at each centre/institution
 - details of any amendments required at other centres.
- 4.6 The Secretary will keep on file a copy of each application submitted for ethics approval, including any information sheets, consent forms, research instruments, letters of approval or relevant correspondence in the form in which they are approved and reports (annual and final).

5 DEFINITIONS

- 5.1 Terms not defined in this document may be in the University [glossary](#).

6 RELATED LEGISLATION AND DOCUMENTS

[Guidelines under Section 95 of the Privacy Act 1988](#)

[Human Research Ethics Committee Grievance Procedure](#)

[Human Research Ethics Committee Terms of Reference](#)

[National Statement on Ethical Conduct in Human Research 2007](#)

7 FEEDBACK

7.1 University staff and students may provide feedback about this document by emailing policy@cqu.edu.au.

8 APPROVAL AND REVIEW DETAILS

| Approval and Review | Details |
|--|-----------------------------------|
| Approval Authority | Academic Board |
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| Administrator | Deputy Vice-Chancellor (Research) |
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