HUMAN RESEARCH ETHICS COMMITTEE MONITORING POLICY AND PROCEDURE

CONTENTS

1 PURPOSE

1.1 This policy and procedure provides guidance to the Human Research Ethics Committee on how to monitor the progress of approved research projects.

2 SCOPE

2.1 This policy and procedure applies to staff and students conducting research involving the use of humans, use of human material, and use of data or records from which individual subjects may be identified.

3 POLICY STATEMENT

3.1 This policy and procedure ensures CQUniversity compliance with the National Statement on Ethical Conduct in Human Research 2007 (the National Statement) which requires the Human Research Ethics Committee to monitor the progress of approved research projects in order to determine that research protocols are preserved in the form in which they were approved.

4 PROCEDURE

Responsibility

4.1 Investigators must comply with ethical principles of integrity, respect for persons, justice and beneficence.

4.2 The Chief Investigator is responsible for:

- notifying the review body (Human Research Ethics Committee) that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research (as per clause 5.5.4 of the National Statement), and
- providing regular (at least annually and at the completion of the project) reports to the relevant review body, including information on:

- progress to date, or outcome in the case of completed research
- maintenance and security of records
- compliance with the approved proposal
- compliance with any conditions of approval (as per clause 5.5.5 of the National Statement), and/or
- notifying the Human Research Ethics Committee of any adverse events or unexpected outcomes (as per clause 5.5.3 of the National Statement).

Responsibility of the human research ethics committee

4.3 Institutions are responsible for monitoring research conducted by its researchers (as per clause 5.5.1 of the National Statement). 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.

4.4 As part of the notification that ethical clearance has been granted, researchers are advised that final reports are required to be submitted one month after the completion date for all projects.

4.5 Additionally, annual reports will be required for projects of greater than 12 months duration, and will be due on the anniversary date of approval date. .

4.6 Researchers are also advised of their responsibility to report on any adverse events or unexpected outcomes within 24 hours of the event.

4.7 The Chair reserves the right to 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.

4.8 The Committee Secretary shall maintain a register of inspection visits.

Reporting of adverse occurrences

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

4.10 The Committee shall ensure that the following condition of approval for any research project is included in any formal advice to the Chief Investigator:

"you advise the Human Research Ethics Committee (email ethics@cqu.edu.au) immediately if any complaints are made, or expressions of concern are raised, or any other issue in relation to the project which may warrant review of ethics approval 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*)."

4.11 The Chair shall 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
- suspend approval for a research project/teaching activity and advise the researcher/s or student/s and supervisor, the Deputy Vice-Chancellor (Research) and any other formal parties to the project to this effect in writing
- restore approval for a research project/teaching activity and advise the researcher/s or student/s and supervisor, the Deputy Vice-Chancellor (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, and

- refer instances of misconduct to the Deputy Vice-Chancellor (Research) for review and/or action in accordance with the CQUniversity Code of Conduct for Research.

4.12 The Chair shall report on any matters involving adverse occurrences at the next meeting of the Human Research Ethics Committee and shall seek ratification of any withdrawal of approval or restoration of approval.

Non-compliance with the code

4.13 Where inspections detect activities of non-compliance with the National Statement or approval conditions, the Secretary or monitoring Committee members must report immediately to the Committee Chair.

4.14 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 adverse occurrence or unforeseen event
- withdraw approval for a research project/teaching activity and advise the researcher/s or student/s, the Deputy Vice-Chancellor (Research) and any other formal parties to the project to this effect in writing
- recommend to the Deputy Vice-Chancellor (Research) that a project/activity be suspended, discontinued or that other necessary steps be taken, and
- restore approval for a research project/teaching activity and advise the researcher/s or student/s, the Deputy Vice-Chancellor (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.

4.15 In the event that the Committee has determined that a project is not being conducted or cannot be conducted in accordance with the approved protocol, the Committee shall refer the project to the Deputy Vice-Chancellor (Research) for review and/or action in accordance with the CQUniversity Code of Conduct for Research.

4.16 The Committee shall formally advise the researcher/s or student/s, Deputy Vice-Chancellor (Research) and Secretary of any withdrawal of approval and recommend to the Deputy Vice-Chancellor (Research) that the research project be discontinued, suspended or that specified steps be taken to allow the project to continue.

5 RESPONSIBILITIES

Compliance, monitoring and review

5.1 The Human Research Ethics Committee Secretary will be responsible for ensuring this policy and procedure is followed.

Reporting

5.2 The Human Research Ethics Committee reports annually to the National Health and Medical Research Council and the Research Committee

Records management

5.3 Staff must maintain all records relevant to administering this policy and procedure in a recognised University recordkeeping system.

6 DEFINITIONS

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

7 RELATED LEGISLATION AND DOCUMENTS

Code of Conduct for Research

National Statement on Ethical Conduct in Human Research (2007)

8 FEEDBACK

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

9 APPROVAL AND REVIEW DETAILS

Approval and Review	Details
Approval Authority	Academic Board
Advisory Committee to Approval Authority	Research Committee
Administrator	Deputy Vice-Chancellor (Research)
Next Review Date	13/06/2021

Approval and Amendment History	Details
Original Approval Authority and Date	Academic Board 13/07/2011
Amendment Authority and Date	Procedure amended Academic Board 3/10/2012; Academic Board 15/07/2015 (combined policy and procedure); Minor update to titles 1/07/2016; Amended and updated to current template – Deputy Vice-Chancellor (Research) 03/04/2017; Research Committee 13/06/2018.
Notes	