

# Human Research Ethics Committee Operating Guidelines



## Definitions

**The Code:** the *Australian Code for the Responsible Conduct of Research*

**Conflict of interest:** a conflict of interest exists where an independent observer might reasonably conclude that the professional actions of a person or institution are or may be unduly influenced by other interests

**DVC (R&I):** Deputy Vice-Chancellor (Research and Innovation)

**The National Statement:** the *National Statement on Ethical Conduct in Human Research*

**Research:** as defined in the *Australian Code for the Responsible Conduct of Research*

## 1. Purpose

The University of the Sunshine Coast Human Research Ethics Committee (UniSC HREC) Operating Guidelines aim to support the effective governance and operation of the HREC to enable the HREC to comply with the National Statement and relevant institutional policies and to promote competent and timely ethical review of human research.

## 2. Meeting frequency

The HREC will meet at least quarterly, ensuring that the frequency of meetings is sufficient to allow for effective functioning of the HREC.

The annual schedule of meetings and closing dates for applications will be advertised to staff and students.

## 3. Administrative processes

The HREC Secretary is responsible for providing administrative support, including the processing of submissions made to the HREC.

Document templates will be available to assist applicants to:

- make an application for ethical review
- request an amendment to an approved project
- report on the annual progress of an ongoing project
- report an adverse event
- report on an approved project or activity that has been completed or discontinued.

## 4. Preparation of minutes and agendas

The HREC Secretary will consult with the HREC Chairperson in preparing minutes and agendas for the HREC.

The secretary will be responsible for final preparation, distribution and record-keeping of all minutes, agendas and associated agenda documents.

Members may request that an item be placed on the agenda.

## 5. Distribution of papers prior to meetings

Papers for HREC meetings shall be despatched by the secretary electronically to members at least seven days in advance of any scheduled meeting.

## 6. Timely review

The HREC will provide competent, fair, consistent and timely review of applications, amendments, reports and standard operating procedures related to human research.

Where practicable, HREC meetings will be scheduled to enable timely consideration of applications in relation to key dates for research grants and degrees.

The HREC will aim to give its initial consideration of a submission by no later than four weeks after receipt, and to complete final consideration by no later than eight weeks after its receipt.

## 7. HREC decisions

The HREC may decide that:

- a. An application to commence a project or activity, or amend an approved project or activity, is either: approved with or without conditions; deferred subject to modification and/or clarification; or not approved.
- b. Following review of the annual report for an approved project or activity and possible consultation with the applicant, the approval for the project or activity is continued, suspended, modified or discontinued.
- c. An approval is suspended or withdrawn.

A more detailed description of the decision categories available to the HREC following the review of an application, amendment or report are detailed in the table below.

Description	Application status	Action to be taken
Approved	No revisions required. Standard approval conditions apply.	Approval correspondence to be sent with standard conditions.
Approved with conditions	No revisions required. Standard approval conditions and additional specific conditions apply.	Approval correspondence to be sent with standard and specific conditions.
Approved subject to Office of Research review of response to feedback	Minor revisions required in response to: minor administrative issues.	Feedback correspondence to be sent with list of required revisions. Approval correspondence to be sent once the Office of Research is satisfied with the response to feedback.
Approved subject to HREC Chairperson and/or Lead Reviewers review of response to feedback	Minor revisions required in response to: <ul style="list-style-type: none"><li>• minor ethical issues and/or</li></ul> minor administrative issues.	Feedback correspondence to be sent with list of required revisions. Approval correspondence to be sent once the HREC Chairperson and/or Lead Reviewers are satisfied with the response to feedback.

<p>Not approved HREC to review response to feedback</p>	<p>Major revisions required in response to:</p> <ul style="list-style-type: none"> <li>• significant methodological issues</li> <li>• significant ethical issues and/or</li> <li>• significant administrative issues.</li> </ul>	<p>Feedback correspondence to be sent with list of required revisions.</p> <p>Response to feedback to be reviewed by the HREC.</p>
<p>Not approvable</p>	<p>Not approvable due to:</p> <ul style="list-style-type: none"> <li>• significant inattention to methodological, ethical and/or administrative issues or</li> <li>• major ethical, reputational and/or scientific merit concerns.</li> </ul> <p>New application required.</p>	<p>Applicants to be advised that ethics approval is not able to be granted.</p> <p>HREC Chair or delegate to discuss issues with applicant as required.</p> <p>New application to be submitted for HREC review.</p>

## 8. Methods of decision-making

The HREC must consider and approve applications for new projects and activities and consider the ongoing approval for existing projects and activities at quorate meetings of the HREC.

The HREC must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant. The HREC may use information in addition to that obtained from the applicant.

The HREC must make a judgement on whether the proposed or continued use of human participation is ethically acceptable. This judgement must:

- a. be based on information provided by the applicant that demonstrates the application of the principles outlined in the National Statement
- b. balance whether the potential risks to human participants are justified by the potential benefits.

The HREC may only approve those projects and activities that are ethically acceptable and conform to:

- the requirements of the National Statement
- any relevant state or federal legislation
- any relevant university policy.

The HREC may invite an applicant to attend a HREC meeting for the agenda item in which the application is to be considered.

The HREC may invite the chief investigator to attend a HREC meeting for the agenda item in which that project is to be the subject of a decision (e.g. amendment to a project).

Decisions made by the HREC should be based on a thorough, fair and inclusive process of discussion and deliberation by HREC members and should only be made by those present throughout the discussion.

Decisions should be made by consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the HREC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still not achieved, the HREC should only proceed to a majority decision (assent by two thirds of the members) after members have been allowed time to review their positions, followed by further discussion.

In determining the duration of approval for individual projects, the HREC should consider the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the institution and funding bodies.

## **9. Committee member sitting fees**

Sitting fees will be paid to members of the HREC who are external to UniSC and who do not already receive compensation (either financial or non-financial) for serving on the committee. The fee will only be paid to members who contribute to reviewing applications and who attend full meetings. The sitting fee is also to assist members with other costs that may arise from being a member, such as parking costs associated with attending a physical meeting or fuel to travel to meetings. No part payments or payment for non-attendance will be provided.

## **10. Prompt notification of decisions**

The HREC will communicate its decisions, the reasons for its decisions, and any conditions attached to an approval to applicants in writing as promptly as possible via the HREC Secretary. Where possible, this will be actioned within ten working days of any decision.

## **11. Monitoring of research projects**

As part of its consideration of each research protocol, the HREC will determine the frequency and type of monitoring required for each research project according to the degree of risk to participants in the research project.

The secretary will be responsible for ensuring that the monitoring occurs as determined, and that monitoring reports are presented to the HREC.

## **12. Adverse events and emergencies**

Guidelines for actions required in the case of adverse events and emergencies will be made available to investigators to ensure that adverse impacts on human participants are addressed promptly.

These guidelines will include timeframes for actions and prompt reporting to the HREC.

The HREC will ensure that the following condition of approval for any research proposal is included in any formal advice to the proposer of an approved research protocol:

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

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

A written report of any adverse occurrence or unforeseen event that might affect the continued ethical acceptability of the research project must be submitted to the HREC Chair by no later than the next working day after recognition of an adverse occurrence/effect.”

The chairperson will have delegated authority to:

- Consult with any other members of the HREC and any other parties to seek advice and assistance in addressing matters arising from any report of adverse or unforeseen event.
- Withdraw approval for a research project and advise the researcher(s), the DVC (R&I), and any other formal parties to the research project to this effect in writing.
- Recommend to the DVC (R&I) that a research project be suspended, discontinued or that other necessary steps be taken.
- Restore approval for a research project and advise the researcher(s), the DVC (R&I), 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.

The chairperson will report on any matters involving adverse occurrences at the next HREC meeting and will seek ratification of any withdrawal of approval or restoration of approval.

### **13. Complaints and non-compliance**

As per the *Human Research Ethics – Governing Policy* and the *Human Research Ethics - Procedures*, complaints and non-compliance are managed in accordance with the Code, the National Statement and where appropriate the *Responsible Research Conduct – Governing Policy and Managing and Investigating Breaches of Responsible Research Conduct - Procedures*.

### **14. Withdrawing HREC approval for a project**

If the HREC determines that a project is not being conducted, or cannot be conducted, in accordance with the approved protocol, and that welfare and rights of the participants are not or will not be protected, the HREC will withdraw its approval.

The HREC will formally advise the researcher(s) and the DVC (R&I) of any withdrawal of approval and recommend that the project be discontinued, suspended, or that specified steps are taken to allow the project to continue.

### **15. Fees**

The HREC will only consider projects and protocols that are being undertaken by USC staff or students. No application fees are charged.

### **16. Confidentiality of the content of protocols and committee proceedings**

Applications submitted for approval will remain confidential to the HREC, any persons from whom expert advice is sought by the HREC, and its secretary.

Registry files for each application will be accorded high security status.

Minutes, agendas and committee papers will remain confidential to the HREC, except as required by law and where specified extracts from minutes or documents are authorised by the HREC to be conveyed to:

- an applicant seeking ethical approval
- a research funding body
- an expert adviser to the HREC
- to university committees for reporting purposes, and
- the DVC (R&I) or delegate in the event of a complaint concerning a research project or irreconcilable difference with the HREC.

### **17. Management of potential conflict of interest**

The potential for a conflict of interest arises when a committee member has any interests that could influence, or appear to influence, the objectivity of a decision during the course of their duties as a member of the HREC.

A conflict of interest, whether perceived, potential, or actual must be declared and addressed.

Where a member of the HREC considers that they have a possible conflict of interest, they are encouraged to consult with the chairperson before the meeting.

Where a member considers that another member may have a conflict of interest in relation to a specific issue on the agenda, they are encouraged to discuss the matter with the chairperson and the other member before the meeting.

Where a member of the HREC has not advised the chairperson of a possible conflict of interest before the meeting, they must declare this possible conflict of interest before the consideration of the specific matter.

At the commencement of each meeting the chairperson will ask members to disclose any potential conflict of interest in any application or other matter being discussed by the HREC.

Those with a possible conflict of interest will absent themselves from the meeting for the duration of the

matter under consideration and not take part in any inspection, review, monitoring or decision-making relevant to the conflicted matter.

For decision making, members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum.

If it is subsequently found that a member of the HREC has not declared a conflict of interest on a specific matter, the chairperson shall notify the DVC (R&I) with a view to a caution being issued to the member or, if considered necessary, further disciplinary action being taken.

#### **18. Providing advice and recommendations to the institution**

The HREC will provide advice and recommendations to the institution, via the DVC (R&I), regarding human research conducted on behalf of the institution, and strategies required to ensure that the requirements of the National Statement are maintained and that matters affecting human participants are addressed.

#### **19. Reporting**

The HREC will submit a written report on its operations at least annually to the governing body of the institution(s) for which it acts. The report will advise on:

- a. numbers and types of projects assessed, approved and rejected
- b. actions that have supported the educational and training needs of HREC members and people involved in human research
- c. administrative or other difficulties experienced
- d. any matters that may affect the institution's ability to maintain compliance with the National Statement and, if appropriate, suitable recommendations.

The HREC will perform other duties as required, including the provision of training and reports for or on behalf of the university.

#### **20. Record-keeping**

The secretary shall maintain records for each application submitted to the HREC, including:

- a copy of the application submitted for approval
- written correspondence of HREC decisions regarding the application, including any conditions of approval
- any other written correspondence to researchers about the application
- responses by researchers to correspondence received from the HREC
- permits, licences or other relevant documentation or correspondence in the form in which they are approved
- annual and final reports on approved projects
- requests for amendments to approved projects, and any resulting decisions by the HREC
- whether the opinion of another HREC was considered
- action taken by the HREC to monitor the conduct of an approved project
- records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes
- any adverse event reports and details of actions taken in consequence
- any complaints received by any relevant personnel.

The secretary will maintain a record of HREC membership and associated documentation. The secretary will maintain other relevant records regarding human research ethics including:

- relevant university policies and procedures, including the committee's terms of reference and operating guidelines
- a register of all projects submitted to the HREC
- agendas and minutes of HREC meetings, including decisions and other aspects of the HREC's operation
- reports to the university on the operations of the HREC and other relevant information concerning human research ethics at the university
- reports to external bodies about the operations of the HREC or other relevant information concerning human research ethics at the university
- registration with the National Health and Medical Research Council (NHMRC)
- internal and external reviews of human research ethics at the university
- relevant state and Commonwealth legislation.

### **Revisions**

Approved: Human Research Ethics Committee, meeting 1 2000, Resolution H00/1, 10/10/2000 Last

Revised: Human Research Ethics Committee, Meeting 01/2019, 12 February 2019

### **Related documents**

- HREC Terms of Reference
- Conflict of Interest - Governing Policy
- Enterprise Risk Management - Governing Policy
- Human Research Ethics - Governing Policy
- Human Research Ethics - Procedures
- Responsible Research Conduct – Governing Policy
- Research Data Management - Procedures
- Managing and Investigating Breaches of Responsible Research Conduct - Procedures
- Staff Code of Conduct - Governing Policy
- Student Academic Integrity - Governing Policy
- Working with Vulnerable People - Managerial Policy

### **Related legislation/standards**

- *Australian Code for the Responsible Conduct of Research*
- *National Statement on Ethical Conduct in Human Research*
- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities*