

Human Research Ethics - Governing Policy

1. Purpose of policy

1.1 The purpose of this policy and its associated procedure is to facilitate the design and conduct of excellent research that adheres to the national human research ethics values and principles. It aims to assist researchers to consider their ethical responsibilities with regards to the design and conduct of their research, to guide researchers in the correct ethical review pathways, to inform the University community of institutional responsibilities regarding human ethics, and to articulate the responsibilities of those involved in the ethical review and related protocols.

2. Policy scope and application

1.2 This policy applies to all staff and students who conduct human research under the auspices of the University. It also applies to the USC Human Research Ethics Committee (USC HREC) and all staff involved in the ethical review of proposed research and related protocols.

3. Definitions

Please refer to the University's Glossary of Terms for policies and procedures. Terms and definitions identified below are specific to this policy and are critical to its effectiveness.

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

Ethical values and principles: the values and principles that the *National Statement on Ethical Conduct in Human Research* indicates need to be addressed in the design, ethical review and conduct of human research. These are: research merit and integrity; respect; beneficence; and justice.

Ethical review: the review of proposed research, with regards to its adherence to the *National Statement* and *Human Research Ethics Guidelines*.

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

Human research: any research activity with or about human participants, including their data or tissue. This covers but is not limited to anonymous surveys, observation of public behaviour, interviews, focus groups, behavioural tests, action research, exercise testing, exploration of sensitive personal behaviour and attitudes, clinical research, and clinical trials.

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

Human Research Ethics Guidelines: a University resource for researchers that outlines the University's interpretation and implementation of the National Statement and provides a transparent policy basis for the conduct of ethical review. The guidelines are available on the Student Portal for staff and research students.

USC HREC: the University of the Sunshine Coast Human Research Ethics Committee. The HREC terms of reference and operating guidelines have been developed in accordance with the National Statement. The USC HREC plays an important role in the University's human research ethics arrangements, but is not solely responsible for the efficient, timely and quality operation of those arrangements, as this is also a key function of the Office of Research.

4. Policy statement

4.1 This policy is to promote the highest ethical standards in the University's human research activity and is an important element of the implementation of and compliance with the National Statement, which is the national policy reference for human research ethics in Australia. This policy contributes to the support of best practice in the conduct of research as described in the Code.

APPROVAL AUTHORITY

Council

RESPONSIBLE EXECUTIVE MEMBER

Deputy Vice-Chancellor (Research and Innovation)

DESIGNATED OFFICER

Director, Office of Research

FIRST APPROVED

7 December 2010

LAST AMENDED

22 April 2022

REVIEW DATE

22 April 2027

STATUS

Active

5. Principles

5.1 All human research must be designed with an awareness of the ethical values and principles outlined by the Code, the National Statement, and the Human Research Ethics Guidelines.

5.2 The principles and guidance material must be used in a thoughtful and project-specific manner, which is relevant for the research topic, potential participant pool, risks and ethical sensitivities.

5.3 Researchers must regard the following expectations as a key factor in establishing the quality of their work and strive to:

- (a) safeguard the welfare, safety and interests of participants;
- (b) only conduct human research when they have the requisite skills, experience, resources and facilities to do so; and
- (c) base research designs on a thorough review of the literature (where it exists) and sound methodology.

5.4 Institutional responsibilities

5.4.1 In accordance with section five of the National Statement, the University has a responsibility to:

- (a) ensure that any human research conducted under the auspices of the University is designed and conducted in accordance with the Code and ethically reviewed and monitored in accordance with the National Statement;
- (b) be satisfied that its human research meets relevant scholarly or scientific standards, and that those conducting its human research are either adequately experienced and qualified or supervised, understand the need to assess risks to their own safety and that of participants, and are free to withdraw from research on conscientious grounds;
- (c) establish processes for ethical review of research;
- (d) be satisfied that processes are in place for managing conflicts of interest, monitoring research, handling complaints and ensuring accountability; and
- (e) use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.

5.5 Ethical review

5.5.1 All human research proposals must be submitted to the Office of Research for review via one of the ethical review pathways outlined in Human Research Ethics – Procedures.

5.5.2 Research (specifically participant recruitment and data collection) must not commence until approval via one of the ethical review pathways has been granted in writing.

5.5.3 All ethical review is to be timely, efficient and transparent. The review must be based upon the content of the National Statement, using ethical principles outlined in the Human Research Ethics Guidelines and the qualifying criteria and processes outlined above and in detail in the Human Research Ethics – Procedures.

5.5.4 The conduct of the review should be collegiate, with the aim of facilitating research.

5.5.5 Where clarification, elaboration, modification, or a major change in approach is required, this should be in line with the National Statement and/or the Human Research Ethics Guidelines, and helpful guidance provided as to useful approaches.

5.6 Ethical conduct of research

5.6.1 The conduct of a human research project must comply with the protocol approved by the ethical review process, as well as the conditions of ethics approval stipulated by the ethical review body or university.

5.6.2 All members of a research team have shared responsibility for the ethical conduct of research and must be aware of and satisfied with the degree to which the conduct of the research meets the national requirements and university policy.

5.6.3 The chief investigator (who must be a University staff member) has ultimate responsibility for the ethical conduct of the project and is responsible for ensuring that all personnel involved in human research or other relevant activities are competent, receive appropriate training for the procedures they perform, and are adequately supervised by a competent person.

5.6.4 Human research activities will be monitored by reviewing progress reports for all approved projects, and by any other means deemed necessary or appropriate, such as random audits.

5.7 Reporting

5.7.1 The USC HREC meeting summaries are provided to Research Committee and Academic Board following each ethics committee meeting. The HREC Chairperson may report separately on other ethics matters as deemed necessary.

5.7.2 The USC HREC annual report is provided to Research Committee, Academic Board and the Audit and Risk Management Committee as per the HREC Terms of Reference. The HREC Chairperson may be invited to attend Research Committee to present the annual report.

6. Authorities/Responsibilities

6.1 The following authorities/responsibilities are delegated under this policy:

ACTIVITY	UNIVERSITY OFFICER/COMMITTEE
Review and determine whether to approve human research applications. Monitor human research projects by reviewing progress reports for all approved projects, and by any other means deemed necessary or appropriate.	Human Research Ethics Committee
Shared responsibility for the ethical conduct of research and must be aware of and satisfied with the degree to which the conduct of the research meets the national requirements and university policy.	Members of the research team
Ultimate responsibility for the ethical conduct of the project and is responsible for ensuring that all personnel involved in human research or other relevant activities are competent, receive appropriate training for the procedures they perform, and are adequately supervised by a competent person.	Chief Investigator

END

RELATED DOCUMENTS

- Conflict of Interest - Governing Policy
- Enterprise Risk Management - Governing Policy
- Human Research Ethics - Procedures
- Managing and Investigating Breaches of Responsible Research Conduct - Procedures
- Research Data Management - Procedures
- Resolution of Complaints (Staff) - Guidelines
- Responsible Research Conduct - Governing Policy
- Staff Code of Conduct - Governing Policy
- Student Conduct - Governing Policy

LINKED DOCUMENTS

- Human Research Ethics - Procedures

RELATED LEGISLATION / STANDARDS

- Australian Code for the Responsible Conduct of Research (2018)
- National Statement on Ethical Conduct in Human Research
- Ethical conduct in research with Aboriginal & Torres Strait Islander Peoples & communities: Guideline
- Human Rights Act 2019 (Qld)