

1. Purpose of policy

This policy is to promote the highest ethical standards in the University's human research. The policy aims to assist researchers to consider their ethical responsibilities with regards to the design and conduct of their research, and to clearly articulate the responsibilities of those involved in the ethical review and related protocols.

This policy is an important element of the University's implementation of and compliance with the National Statement on Ethical Conduct in Human Research, which is the national policy reference for human research ethics in Australia. This policy also contributes to the support of best practice in the conduct of research as described in the Australian Code of Conduct for the Responsible Conduct of Research.

A key principle and purpose of this policy is to facilitate the design and conduct of excellent research that adheres to the national human research ethics values and principles.

2. Policy scope and application

This policy applies to all USC 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.

Australian Code means the Australian Code for the Responsible Conduct of Research, which was developed jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia.

Ethical values and principles means 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 means the prior review of proposed research, with regards to its adherence to the National Statement and Human Research Ethics Guidelines.

Research means the creation of new knowledge and/or the use of existing knowledge in a new and creative ways to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes.

Human research means 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 means the National Statement on Ethical Conduct in Human Research released by the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) and endorsed by Universities Australia. Institutional compliance with the National Statement is a condition of eligibility for ARC and NHMRC funding, as well as many other funding bodies. Adherence with the National Statement is an expectation of membership of Universities Australia, is increasingly a condition of publication in academic journals, and is often a condition of access to populations (e.g. students in Education Queensland schools).

Human Research Ethics Guidelines is a USC 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 MyUSC for staff, and on Blackboard for research students.

APPROVAL AUTHORITY

Council

RESPONSIBLE OFFICER

Deputy Vice-Chancellor (Research and Innovation)

DESIGNATED OFFICER

Director, Office of Research

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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

Responsible Research Conduct - Governing Policy

Staff Code of Conduct - Governing Policy

Student Conduct - Governing Policy

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 and Torres Strait Islander Peoples and communities

USC HREC means 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. Institutional responsibilities

4.1 In accordance with section five of the National Statement, USC has a responsibility to:

4.1.1 Ensure that any human research conducted under the auspices of the University is designed and conducted in accordance with the Australian Code, and ethically reviewed and monitored in accordance with the National Statement.

4.1.2 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.

4.1.3 Establish processes for ethical review of research.

4.1.4 Be satisfied that processes are in place for managing conflicts of interest, monitoring research, handling complaints, and ensuring accountability.

4.1.5 Use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.

5. Ethical principles in the design of research

5.1 All university human research must be designed with an awareness of the ethical values and principles outlined by the Australian 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:

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

6. Ethical review

6.1 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.

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

6.3 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.

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

6.5 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.

7. Ethical conduct of research

7.1 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.

7.2 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.

7.3 The chief investigator (who must be a USC 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.

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

8. Reporting

8.1 The USC HREC provides quarterly reports to the Research Committee covering ethics matters outlined in the Research Committee's terms of reference. The reports will also include any other information that the HREC Chairperson deems relevant.

8.2 The USC HREC provides an annual report to the Academic Board, via the Research Committee. The HREC Chairperson may be invited to attend the Research Committee to present the annual report.

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