Human Research Ethics Procedure

1 Purpose

To establish an institutional framework for the ethical conduct of Human Research at the University.

2 Scope

This procedure applies to UniSQ Researchers, UniSQ Human Research Ethics Committee (HREC) members and professional staff supporting the administration of ethics at the University.

3 Procedure Overview

This procedure outlines the University processes related to the ethical review, approval, monitoring, and conduct of Human Research and should be read in conjunction with the most recent versions of the Australian Code for the Responsible Conduct of Research, and the National Statement on Ethical Conduct in Human Research. Compliance with the National Statement on Ethical Conduct in Human Research is a prerequisite for receipt of National Health and Medical Research Council funding.

4 Human Research Ethics Review

The University acknowledges that Human Research includes a wide range of activities with an equally wide range of potential risks and potential benefits. The National Statement on Ethical Conduct of Research allows for different levels of ethical review of research and exemptions from ethical review, reflecting the differences in the degree of potential risk involved. All proposed Human Research conducted by Researchers must obtain either (a) ethical approval, or (b) exemption from ethical review.

Researchers undertaking cross-institutional projects who are approved to undertake research by another HREC, must ensure that they also seek approval from the University.

Human Research must meet the requirements of the National Statement on Ethical Conduct of Research and be deemed ethically acceptable before it can commence. It must:

- meet relevant scholarly or scientific standards; and
- be conducted by Researchers that:

- are either adequately experienced and qualified, or supervised;
- understand the requirement to assess risks to both their own safety and that of participants; and
- are free to withdraw from research on conscientious grounds.

Human Research should cease if the approval is suspended, withdrawn, or expired by either the University or the ethical review process.

4.1 Exemption from Human Research ethical review

The following types of human research may be exempt from ethical review:

- use of existing collections of data or records that contain only non-identifiable data about human beings; and/or
- research deemed to pose Negligible Risk to a participant.

Advice on exemption should be sought from the Ethics team in the Office of Research.

4.2 Human Research Ethics Committee

The University of Southern Queensland Human Research Ethics Committee (UniSQ HREC) has been established in compliance with the National Statement on Ethical Conduct in Human Research. The UniSQ HREC is registered with the National Health and Medical Research Council.

The UniSQ HREC operates in accordance with the minimum membership requirements set out by the National Statement on Ethical Conduct in Human Research. The UniSQ HREC may invite and/or appoint additional people with specific expertise to provide advice to the committee, as required. In the event the UniSQ HREC does not have the required expertise, constitution and/or it is not functioning according to the National Statement on Ethical Conduct in Research, the UniSQ HREC will refer applicants to the NHMRC list of registered institutions to find an appropriate HREC to review the matter.

4.2.1 Membership

The appointment and reappointment of members will be an open and transparent process reflective of Section 5 of the National Statement on Ethical Conduct of Research and outlined on the University's Human Ethics webpages.

Appointments will not exceed three years and will be made on the basis of individual knowledge, qualities, and experience. Where required, specific role training will be provided by the Ethics team to members following their appointment.

A member who fails to uphold their duties in accordance with their letter of appointment may have their membership suspended or discontinued by the Chair, UniSQ HREC. If the concern relates to the Chair, the matter will be referred to the Deputy Vice-Chancellor (Research and Innovation). Written notification of the suspension or discontinuation of ethical review membership will be provided.

4.3 Non-HREC ethical review

The University will establish and operate levels of non-HREC ethical review for Human Research that involve negligible or low risk and do not fall under prescribed chapters of the National Statement on Ethical Conduct in Human Research that require review by a HREC.

The UniSQ HREC may choose to appoint one or more ethical reviewers to non-HREC ethical review from existing members of the UniSQ HREC, staff associated with the Human Research ethics function at the University, or other appropriately qualified individuals.

4.4 Responsibilities

University	Specific responsibilities for the University include, but are limited to: • Ethical review process is resourced appropriately to ensure that they are conducted competently and professionally. • Appropriate training and resources are provided to: ◦ UniSQ HREC members in relation to policies and guidelines relevant to Human Research ethics and the business of the University. ◦ Researchers to support their understanding of Human Research Ethics and the ethical review process. • Development, documentation and implementation of local work processes to promote good ethical review.
UniSQ HREC members and Human Research ethical review members	Human Research ethical review members should: • be familiar with the National Statement on Ethical Conduct in Human Research;

	• commit to attend continuing education and training in research ethics activities provided by the University; • declare and manage any perceived, potential, or real conflict of interest that could influence the objectivity of their Decision making prior to any deliberation of the ethical acceptability of Human Research; • maintain confidentiality regarding the content of items under review and any other matter under consideration for ethical acceptability of Human Research in accordance with the UniSQ HREC Confidentiality Agreement; • decide, in their own judgement, whether an Item Under Review or any other matter under consideration for ethical acceptability of Human Research is ethically acceptable and meets the requirements of National Statement on Ethical Conduct in Human Research; and • provide their written opinion on the ethical acceptability of items under review within the timelines defined and communicated by the Committee.
UniSQ HREC Chair	In addition to the responsibilities outlined for Human Research ethical review members and UniSQ HREC members, the UniSQ HREC Chair, with assistance from the Deputy Chair/s, is responsible for: • impartially guiding the operation of the UniSQ HREC; • deciding, in their own judgement, whether a Negligible or Low-Risk Human Research ethics application, Negligible or Low-Risk Human Research amendment application, a reciprocal HREC approval arrangement, or any other items under review referred to the UniSQ HREC Chair by the UniSQ HREC or University established Human Research ethical review process is ethically acceptable; and • representing the UniSQ HREC in any negotiations with the University management.
Researchers	A Researcher proposing to conduct Human Research must demonstrate the proposed research has merit and reflects the ethical values of justice, beneficence, and respect for humans. The application template developed by the University will contain key questions that must be adequately addressed by applicants to ensure that requirements of the National Statement on Ethical Conduct in Human Research are met.

For proposed health research, a Researcher must also demonstrate how the research meets the requirements of:

- the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95); and/or
- ISO 14155 Clinical Investigation of Medical Devises; and/or
- The World Health Organisation International Clinical Trials Registry Platform; and/or
- The Therapeutic Goods Administration.

Following approval, a Researcher must:

- keep an auditable record of the research conduct that has been approved (or exempted from ethical review); and
- manage any actual, perceived, or potential conflict of interest that may bear on the research; and
- disclose any actual or potential conflict of interest or affiliation that may bear on the research when reporting the research; and
- notify the UniSQ HREC or University ethical review process that mechanisms for monitoring are in place and satisfy the review body that the mechanisms are appropriate to the research; and
- report to the UniSQ HREC and the University on:
    - the progress to date, or outcome of completed research; and
    - compliance with the University's Research Data and Primary Materials Management Procedure; and
    - compliance with the approved project; and
    - compliance with any standard or special conditions of approval; and
- inform the UniSQ HREC as soon as possible of any new safety information from published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project; and

	• for clinical trials with implantable medical devices, confirm the existence of, or establish, a system for enabling the tracking of the participant, with consent, for the lifetime of the device.

4.5 Ethical review process

4.5.1 Application preparation and submission

Applicants will be able to access information on how to apply for ethical clearance (including timelines) through the University's Human Ethics website

Applications will not be accepted by the Ethics office until they have been appropriately reviewed at the local level. For example, a Higher Degrees Student application must be reviewed and endorsed by the Student's supervisor prior to being forward to the Head of School or Centre Director for endorsement.

All applications require review and endorsement of the Head of School or Centre Director prior to submission for approval as the Head is responsible for management Decisions that involve the allocation of resourcing, including staffing and financial. Review and approval at this level ensures that research projects being submitted to the UniSQ HREC has been judged to have research merit.

4.5.2 Administrative Review

All applications will undergo an administrative review by the Office of Research. Ordinarily this step will be undertaken within 10 University Business Days and aims to:

- Check for missing information or potential future road blocks for applicants to assist in addressing key issues early in the process (e.g. missing information or attachments, incorrect selections relating to participant groups), and
- Identify risk level

4.5.3 Expedited Review

Research that is deemed to be low or negligible risk and does not fall under any of the National Statement on Ethical Conduct in Human Research chapters listed for a full HREC meeting, can be sent to expedited review. This review process ordinarily can be completed in 20 University Business Days.

The expedited review is completed by at least two experienced reviewers. At least one reviewer will be member of the executive of the UniSQ HREC (i.e. Chair and/or Deputy Chairs). If

required, one of the reviewers can be a skilled and experienced staff member in the Office of Research.

4.5.4 Meetings

Projects involving research considered to be greater than low risk, must be referred to the UniSQ HREC. Meeting dates are published in the University meeting calendar and submission timelines for meetings are made available from the University's Human Ethics website. Submission timelines allow for the need for applications to be assigned to eight different categories of members for their review and feedback prior to a meeting date.

Further details related to the conduct of meetings is outlined in the Committee's terms of reference available from the University's governance website.

4.5.5 Review outcome

At the conclusion of the review process, a Decision will be communicated to the applicant. The outcome from an ethical review process may be:

- Approved (with standard and/or special conditions); or
- Modifications required - Applicants must first address feedback provided through the review process before full approval can be granted); or
- Rejected/Not Approved - Resubmission permitted (with feedback provided for the applicant's consideration prior to revision and submission of a new application); or
- Rejected/Not Approved - Resubmission not permitted.

4.5.6 Applicant Response to Decision

When an application requires modification or has not been approved (resubmission permitted) the applicant is required to:

1. Provide a response to the Decision through:
    a. addressing (or defending) feedback provided from the ethical review process; and

    b. undertaking any revisions to the application, as required.

2. Resubmit the application for approval.

The review process can be a quite involved and time-intensive process for reviewers,

particularly where applications do not address the questions appropriately. Applicants are expected to engage in order to progress their application further. Where an applicant provides limited or no response to feedback provided by reviewers, the UniSQ HREC Chair or UniSQ Deputy Chair will not accept a re-submitted application and it will be returned to the applicant.

Applicants may request to meet, and/or be invited to meet with, the UniSQ HREC Chair, UniSQ HREC Deputy Chair or the Ethics team to discuss ethical review feedback.

4.5.7 Period of approval

Ethical approval for a research project reviewed by a University established process will ordinarily be granted for a three year period. An applicant may request a longer approval period by contacting the Ethics team at the time of application. Extension of ethical approval dates may also be approved as an amendment.

Ethical approval for a research project conducted by a Student within a Masters or Honours program of study will normally be provided for 12 months (or to the end of the current academic year).

4.5.8 Appeal of Decision

There may be justifiable differences of opinion as to whether an application meets the requirements of the National Statement on Ethical Conduct in Human Research. Where there is a disagreement about an outcome of a review, applicants are asked to respectfully seek further advice and clarification from the Committee. If required, a written response or meeting with the Chair may help to clarify matters.

If an applicant would like to proceed with a formal Appeal against a Decision made by a University Human Research ethical review process, it should be noted that Appeals will only be considered on the basis of Procedural Irregularity. Appeals are to be made in writing to the Manager, Research Integrity and Ethics and the Deputy Vice-Chancellor (Research and Innovation).

4.6 Conducting Human Research

All Human Research conducted by a Researcher must be undertaken in accordance with the requirements of the most recent versions of the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, and any supporting guidelines referred to therein.

4.6.1 Amendment to Human Research ethics approval

At times, approved Human Research ethics approvals may require amendment. This may be for reasons such as, but not limited to:

- changes to project protocols and/or methodology;
- participant groups;
- participant information sheets, consent forms, letters of invitation;
- surveys/questionnaires or interview questions;
- investigators on the research team;
- revisions to the approved protocol are to be undertaken in order to eliminate immediate risks to participants;
- the risk to participants may have increased, and/or
- the conduct of the research will (or has been) significantly affected.

The Principal Investigator (as listed on the approved project) is responsible for submission of an amendment application

Approval of an amendment will only occur when the research team have demonstrated that they have complied with their existing approval as outlined in the original approval letter (including submission of all required reports).

4.7 Monitoring Human Research

Research governance arrangements are in place at the University, to monitor approved research. The monitoring arrangements for an approved Human Research project will be commensurate with the risk, size, and complexity of the research and will include review of reports on progress to date, or outcomes achieved (in the case of completed research). Human Research milestone reports are to be submitted via the University's approved research information management system. It is the responsibility of the Principal Investigator of the approved Human Research project to manage the submission of milestone reports by the required date.

Progress Reports:	Milestone Reports on the progress of the approved Human Research must be submitted at least on an annual basis and normally on the anniversary date of ethical approval. Additional reports on progress of approved Human Research may be requested by the UniSQ HREC or University ethical review process, given the level of risk associated with the project, the work to be conducted, experience and qualifications of the research team, and where research to be conducted is proposed to be staged (or dependent on outcomes from earlier stages of the research).
Final Reports:	A milestone report on the conclusion of the approved Human

	Research is to be submitted when the research conduct has been completed or by the ethical approval expiry date (whichever is sooner).

All monitoring reports submitted will be reviewed by the UniSQ HREC Chair (or delegate). A Decision will be communicated to the applicant and will be: Satisfactory (with or without standard and/or special conditions); Further information requested (with feedback provided to the application for resolution prior to re-submission for further review by the delegated ethical review process); or Unsatisfactory.

Where a report is considered unsatisfactory the Principal Investigator is notified of the reasons for this Decision and invited to respond to the comments. Human Research conduct may be suspended and/or revoked until identified matters have been resolved, in accordance with this procedure.

In monitoring approved Human Research, the UniSQ HREC and University established review processes may also undertake interviews with research participants and/or accept other forms of feedback from them

Milestone reports that are not submitted by the due date(s) may result in the ethical approval for the project being suspended and/or revoked.

In monitoring approved Human Research, the UniSQ HREC and University may also choose to conduct announced and/or random inspections of research sites, Research Data, and/or consent documentation.

4.7.1 Clinical Trials

The UniSQ HREC will oversee the progress of a clinical trial to ensure that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice, and the applicable regulatory requirements. If there is an identified need the University, in consultation with the UniSQ HREC, may choose to establish and operate a Data Safety Monitoring Board in accordance with the *NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods* and the supplementary guidance on *Data Safety Monitoring Boards*.

4.7.2 Adverse Events

An adverse event in Human Research is an event that occurs during the conduct of the research that causes, or increases the risk of harm (physical, psychological, social, economic or legal devaluation of personal worth) to a participant, participant group, or other persons associated with the research. Some adverse events may be expected and detailed at the time of the ethics application. Those unforeseen in the application phase or those anticipated that have a greater consequence are typically classified as 'unexpected adverse events'.

Adverse events may occur in clinical trials as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in

participants, users, or other persons. The NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods guidelines will be consulted for advice on categorisation and reporting of adverse events and adverse reactions that occur as part of a clinical trial.

Adverse events should be reported to the UniSQ HREC Committee as soon as possible (ordinarily within 48 hours) and immediate actions taken to ensure the safety of those involved in the research. Adverse events that are sufficiently serious must result in the investigators ceasing to gather data, securing existing data, and if applicably, making the research site safe. If the adverse event is caused by an incident occurs within a University facility, the appropriate report must also be submitted to UniSQ Safe.

4.8 Suspension or Discontinuation of research

The University or the UniSQ HREC Chair (or nominee) may suspend and/or discontinue Human Research ethical approval where there are concerns related to the welfare of participant/s. In this situation, the University will be guided by Chapter 5.5 of the National Statement on Ethical Conduct in Human Research related to discontinuation or suspension of research.

The University or the UniSQ HREC Chair may also suspend and/or discontinue Human Research ethical approval where the Principal Investigator and/or research team fail to comply with conditions of ethical approval. Where Human Research approval has been suspended and/or discontinued:

- The Principal Investigator will inform all relevant institution/s, HREC/s, and participants of the research (where possible) of the suspension/discontinuation.
- The University will notify, where required:
    - project funding bodies (in line with agreed protocols);
    - the National Health and Medical Research Council; and/or
    - other bodies (in line with regulatory requirements).
- The UniSQ HREC Chair will report on any suspension/revocation of Human Research ethical approval to the UniSQ HREC, at the next scheduled meeting.

4.9 Applications from external researchers

Applications may also be accepted from applicants who are not engaged by an Australian organisation that has an affiliated HREC. Acceptance of applications from non-affiliated or independent researchers to a University established ethical review process will be on the basis that the:

- researcher does not have access to a HREC within their organisation;
- research is being conducted within Queensland;
- proposed work is not a multi-centre research project;
- proposed project does not involve a clinical trial of unregistered therapeutic goods or medical intervention; and
- respective University established ethical review process has sufficient resources to adequately review and monitor the proposed research.

Where the ethical review process membership does not have sufficient expertise to review and/or sufficient resources to monitor the proposed research the applicant will be directed to an alternative registered and/or certified HREC, a list of which are outlined on the NHMRC website.

5 Record keeping

Records will be maintained in accordance with the University's Records Governance Management Policy and Procedure. The Office of Research will maintain:

- a register of all applications made for, and documentation pertaining to, Human Research at the University
- the outcomes of all such applications and any deliberations related to those outcomes;
- the outcomes of any other items under review and any deliberations related to those outcomes;
- documentation that record Decisions of the UniSQ HREC and University established non-HREC Human Research review processes;
- minutes and all records relating to the operation of the UniSQ HREC; and
- records of inspections and monitoring activities conducted by the UniSQ HREC.

These records may be made available to persons at the University responsible for research projects involving Human Participants, as required to undertake their work activities, via request in writing to Human.Ethics@usq.edu.au, and in accordance with the University's policies on record-keeping.

Researchers must keep an auditable record of the research conduct that has been approved (or exempted from ethical review); including (but not limited to):

- Research Data (original and analysed);
- Research Data management plan;
- ethical approval or exemption from ethical review;
- Researcher(s) associated with the project and their qualifications, experience, permits, and records of work conducted;
- organisational access approval (if required);
- participant informed consent arrangements;
- dissemination of findings;
- registration of potential, perceived, and actual conflicts of interest; and
- project funding arrangements.

6 Management of Potential Breaches

Conducting Human Research without ethics approval or failing to conduct research as approved is considered a potential breach of the University's Research Code of Conduct. When a Researcher or member of the Ethics team become aware of a potential breach they should review and follow the steps as outlined in the Research Code of Conduct: Management of Potential Breaches Procedure.

7 References

Australian Government. (2018). National Statement on Ethical Conduct in Human Research (2007) - Updated 2018. Canberra, ACT: Australian Government, Retrieved from: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

8 Schedules

This procedure must be read in conjunction with its subordinate schedules as provided in the table below.

9 Procedure Information

Accountable Officer	Deputy Vice-Chancellor (Research and Innovation)
Responsible Officer	Deputy Vice-Chancellor (Research and Innovation)

Policy Type	University Procedure
Policy Suite	Research Code of Conduct Policy
Subordinate Schedules	
Approved Date	29/4/2020
Effective Date	29/4/2020
Review Date	29/4/2025
Relevant Legislation	*Privacy Act 1998* (Cwth) *Information Privacy Act 2009* (Qld)
Policy Exceptions	Policy Exceptions Register
Related Policies	Code of Conduct Policy Records and Information Management Policy Student Grievance Resolution Policy
Related Procedures	Authorship Procedure Research Code of Conduct: Management of Potential Breaches Procedure Research Data and Primary Materials Management Procedure
Related forms, publications and websites	Australian Code for Responsible Conduct of Research, 2018 Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018 Guidelines for Ethical Research in Australian Indigenous Studies Keeping research on track II 2018 National Statement on Ethical Conduct in Human Research (2007), updated 2018 UniSQ Human Research Ethics Application Forms and Resources UniSQ Human Research Guidelines for designing participant information sheets and consent forms
Definitions	**Terms defined in the Definitions Dictionary**

Appeal

A formal, written request made by a Student or Employee to a higher authority to have a Decision overturned.

Decision

A determination made by an Employee, contractor or other authorised delegate in the course of their duties on behalf of the University.

Employee

A person employed by the University and whose conditions of employment are covered by the Enterprise Agreement and includes persons employed on a continuing, fixed term or casual basis. Employees also include senior Employees whose conditions of employment are covered by a written agreement or contract with the University.

Researcher

Any person/s involved in Research Activities at, or on behalf of the University. This includes, but is not limited to Employees, Students, visiting scholars, research partners, research affiliates, holders of Honorary or Adjunct positions.

Student

A person who is enrolled in a UniSQ Upskill Course or who is admitted to an Award Program or Non-Award Program offered by the University and is: currently enrolled in one or more Courses or study units; or not currently enrolled but is on an approved Leave of Absence or whose admission has not been cancelled.

University

The term 'University' or 'UniSQ' means the University of Southern Queensland.

University Business Days

The days of Monday to Friday inclusive between 9am and 5pm Australian Eastern Standard Time (AEST), with the exclusion of gazetted Public Holidays for the relevant campus location, plus the closure of the University between 25 December and 1 January in the following year inclusive as specified in the Enterprise Agreement, as well as any closure of the University either at one or several campuses in accordance with a direction of the Crisis Management

	Team.
	Definitions that relate to this procedure only
	Human Research Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: • taking part in surveys, interviews or focus groups; • undergoing psychological, physiological or medical testing or treatment; • being observed by researchers; • researchers having access to their personal documents or other materials; • the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath; • access to their information (in individually identifiable, re-identifiable or nonidentifiable form) as part of an existing published or unpublished source or database. Source: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1931
Keywords	
Record No	18/1191PL