Human Research Ethics Procedure

1 Purpose

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

2 Scope

This Procedure applies to:

- University Researchers;
- members of the University of Southern Queensland Human Research Ethics Committee (UniSQ HREC); and
- professional staff supporting the administration of Human Research ethics at the University.

3 Procedure Overview

This Procedure outlines the University's processes for the ethical conduct, review, approval, and monitoring of Human Research and should be read in conjunction with:

- the Australian Code for the Responsible Conduct of Research; and
- the National Statement on Ethical Conduct in Human Research 2025 (the National Statement).

4 Procedures

All Human Research conducted by a Researcher must be undertaken in accordance with the requirements 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.

Compliance with the National Statement is a prerequisite for receiving National Health and Medical Research Council (NHMRC) funding.

4.1 Ethics review

The University acknowledges that Human Research encompasses a wide range of activities, each with varying levels of potential Risks and benefits. To reflect these differences, the National Statement allows for different levels of ethics review and exemptions, depending on the degree of potential Risk involved.

All Human Research must undergo ethics review prior to commencement to ensure compliance with the National Statement and to determine whether:

- ethics approval is required; or
- the Research qualifies for exemption from ethics review.

Ethics review ensures that Human Research meets ethical standards and guidelines.

Researchers must submit ethics applications through the University's Research information management system in accordance with the Research Management Procedure. Guidance is available from the Research Integrity and Ethics Team in the Office of Research.

Approval from the UniSQ HREC is still required for Research that has previously received approval from another institution's HREC.

The UniSQ HREC does not currently accept applications from Researchers with no formal affiliation with the University.

4.1.1 Exemption from ethics review

Some Human Research projects may qualify for exemption if they involve minimal Risk and meet one or more of the following criteria:

- uses data that is anonymised and includes safeguards to prevent re-identification;
- is restricted to surveys or observations of public behaviour without identifiable data and is unlikely to cause distress to anyone associated with the process or outcomes of the Research;
- is conducted solely for educational training purposes, where outcomes are not intended for broader dissemination; or
- uses only publicly available information protected by law.

When considering if an exemption may apply, Researchers should seek advice from the Research Integrity and Ethics Team in the Office of Research.

4.1.2 Levels of ethics review

The degree of ethics review required is determined by the level of Risk involved in the proposed Research:

Level of Risk	Description	Review requirements	Additional information
Lower Risk Research	Research that is minimal or low Risk and does not fall under prescribed chapters of the National Statement.	Eligible for non-HREC (expedited) ethics review.	Reviews may be expedited and conducted by existing members of the UniSQ HREC, staff associated with the Human Research ethics function at the University, or other appropriately qualified individuals as appointed by the UniSQ HREC.
Higher Risk Research	Research involving greater than low Risk.	Review by the UniSQ HREC.	Includes Research falling under prescribed chapters of the National Statement that mandate HREC review. Submission deadlines and meeting dates are outlined on the University website.

4.2 Ethics review process

4.2.1 Application preparation and submission

Researchers are responsible for preparing and submitting applications for ethics review through the University's Research information management system.

Before submission to the Research Integrity and Ethics Team in the Office of Research, all applications must undergo local-level peer review as well as endorsement by the Head of School and Dean, or Centre Director (or delegate). This review ensures that the Research meets scholarly and scientific standards and that resources such as staffing and funding have been appropriately considered. Evidence of peer review must be provided for all projects and considered as part of the endorsement process. The Head of School and Dean or Centre Director (or delegate) has the authority to reject applications that are incomplete, unsuitable, or that have not been peer-reviewed.

For Student applications, the role of principal investigator must be assigned to the principal supervisor. Student applications require review and endorsement by the principal supervisor before progressing to local-level review following the processes outlined above.

Applications must be clear, comprehensive, and written in accessible language for ethics review bodies. Poor-quality or incomplete applications will not be accepted and may delay the review process.

Information on the application process, including timelines and resources, is available on the human ethics section of the University website. Training is also made available and communicated to Employees and HDR Students throughout the year.

4.2.2 Administrative review

Once an application is submitted, the Research Integrity and Ethics Team conducts an administrative review to ensure completeness, identify the appropriate Risk level, and address potential issues, such as missing information or misclassification of participant groups. Researchers will be notified of any deficiencies and must address them promptly to prevent delays.

4.2.3 Lower Risk application review

Minimal or low-Risk ('Lower Risk') Research that does not fall under prescribed chapters of the National Statement may undergo non-HREC (expedited) review. The requirements for Lower Risk applications are outlined in Section 4.1.2.

Expedited reviews are conducted by one or more people who are familiar with the National Statement and have an understanding of:

- the ethical issues that can arise in the Research under review;
- issues associated with the collection, use and management of data and information in Research;
- the privacy guidelines that may apply to the Research under review; and
- other legal standards that may apply to the Research under review, such as legislation relating to guardianship or use of human biospecimens.

The expedited review must be informed by guidance provided in the National Statement. During an expedited review, where Risk that is greater than low Risk is identified, the application will be referred to the HREC.

4.2.4 Higher Risk application review

Research classified as greater than low Risk ('Higher Risk') must be referred to the UniSQ HREC for comprehensive review. Submission deadlines and meeting dates are available on the human ethics section of the University website.

The UniSQ HREC is established in compliance with the National Statement and is registered with the NHMRC. The committee ensures that applications meet ethical standards, safeguard participant welfare, and comply with institutional and legal requirements.

Research involving Aboriginal and Torres Strait Islander Peoples must also be conducted in accordance with the following guidelines:

1. Ethical conduct in Research with Aboriginal and Torres Strait Islander Peoples and communities;
2. Keeping research on track II; and
3. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research.

Where necessary, the UniSQ HREC may invite or appoint additional experts to review complex applications. If the UniSQ HREC cannot review an application due to a lack of expertise or other constraints, applicants may be referred to an alternative HREC listed on the NHMRC registry.

Further details on the conduct of meetings are outlined in the UniSQ HREC's terms of reference, available on the governance section of the University website.

4.2.5 Review timelines

The timeline for completing ethics reviews depends on the type of review and the current workload of relevant staff members. Researchers can find expected timelines for different review types on the human ethics section of the University website.

To ensure timely review and approval, Researchers should:

- submit applications well in advance of project commencement; and
- respond promptly to any requests for additional information or modifications.

4.3 Ethics review outcomes

At the conclusion of the ethics review process, Researchers will be notified of the outcome of their application. The possible outcomes are outlined below:

Decision category	Description	Next steps
Approved	The project is approved with standard conditions.	Researchers must comply with all conditions outlined in the approval letter.

Approved (with additional conditions)	The project is approved with standard conditions plus additional conditions specified by the review body.	Researchers must comply with all conditions outlined in the approval letter.
Subject to modifications	Approval is conditional upon the applicant addressing specific feedback from the review body.	The applicant must submit modifications addressing the feedback to allow further review of the project.
Not approved: Resubmission permitted	The application does not meet the requirements for ethics approval in its current form, but feedback is provided for revision.	The applicant may revise and resubmit the application through the appropriate review pathway.
Not approved: Resubmission not permitted	The application does not meet the requirements for ethics approval, and no further revisions will be accepted.	The project cannot proceed, and no resubmissions are permitted.

4.3.1 Notification

At the conclusion of the ethics review process, applicants will be notified of the outcome via the Research information management system. Notifications will include the Decision, any conditions or required modifications, and detailed feedback if applicable.

Applicants who receive a Decision requiring modifications or additional feedback must review the provided information carefully and address or defend any concerns raised. Revisions must align with the ethical principles outlined in the National Statement.

Once revisions are complete, the updated application must be submitted through the Research information management system for further review. If the feedback is not adequately addressed, the application may be returned without further consideration.

Applicants may request to meet, and/or be invited to meet, with the UniSQ HREC Chair, UniSQ HREC Deputy Chair, or a member of the Research Integrity and Ethics Team to discuss review feedback and progress applications.

4.3.2 Period of approval

Ethics approval for Research projects is granted for a specified duration:

- **Three years**: The standard approval period for most Research projects. Applicants requiring a longer approval period must contact the Research Integrity and Ethics Team at the time of application.

- **Twelve months**: Projects conducted by Students in masters or honours programs are typically approved for this shorter duration.

Extensions to the approval period may be granted through an amendment request. Researchers must ensure approval remains current until the project is considered completed (all communication with participants, including the provision of feedback, has been completed). Final reports can be provided even if a thesis or publications are still being written.

4.4 Amendments to ethics approval

Once ethics approval has been granted, Researchers must conduct the Research strictly in accordance with the approved application. Any changes to the approved project must be submitted as an amendment for review and approval before implementation. Conducting changes without prior approval is considered a breach of ethical requirements and may result in suspension or revocation of approval.

Researchers are expected to continue conducting the project as originally approved unless the amendment relates to urgent changes necessary to mitigate immediate Risks to participants or Researchers. In such cases, the principal investigator must notify the Research Integrity and Ethics Team immediately and submit the amendment retrospectively.

Once an amendment is approved, Researchers must:

- update all relevant project documentation to reflect the approved changes;
- notify all affected participants or collaborators if the changes impact them directly; and
- ensure that any new procedures or materials are implemented as per the amended approval.

4.4.1 Reasons for amendments

Amendments to ethics approval may be required for various reasons, including but not limited to:

- changes to the Research protocol, such as modifications to the study design, methodology, or data collection instruments;
- adjustments to participant groups, including changes to recruitment methods, eligibility criteria, or participant numbers;
- revisions to participant-facing materials, such as information sheets or consent forms;
- the addition or removal of Researchers or key personnel from the project;

- changes required to address increased Risks to participants or Researchers; and
- extensions to the approval period to accommodate delays or extended study timelines.

4.4.2 Submission process

The principal investigator is responsible for initiating and submitting amendment requests through the University's Research information management system. The amendment request must include:

- a detailed description of the proposed changes;
- a justification for the amendment, including any associated Risks or ethical considerations; and
- updated documentation, such as revised protocols, participant information sheets, or consent forms.

The ethics review body will assess the amendment to ensure it complies with ethical principles, addresses any new Risks, and aligns with the original project's objectives and approved conditions. Approval of amendments is contingent on the project team's compliance with existing conditions outlined in the original approval letter.

4.5 Monitoring and reporting

The University has established Research governance arrangements to ensure approved Human Research projects comply with ethical standards. Monitoring arrangements are proportionate to the Risk, size, and complexity of the project and include milestone reporting, feedback collection, and potential inspections.

4.5.1 Progress reports

Researchers are required to submit milestone progress reports annually, on the anniversary of their ethics approval date or as specified in their approval letter. These reports must provide:

- a summary of the Research progress, including any changes to the approved protocol or timelines;
- details of any issues or challenges encountered during the Research; and
- steps taken to address Risks or challenges to participants, Researchers, or data integrity.

The UniSQ HREC Chair or an experienced staff member from the Office of Research will review all submitted milestone reports. The outcome of this review will be communicated to the principal investigator and may include:

- approval to continue or confirm project completion;
- a request for further information or clarifications, with feedback provided for resolution; or
- non-approval, with reasons outlined.

If a report is not approved, the principal investigator must respond to the feedback and address any issues before the project can proceed or be deemed complete.

Additional progress reports may be requested by the UniSQ HREC or University ethics review body, depending on factors such as the level of Risk, the staged nature of the project, or the experience and qualifications of the Research team.

Failure to submit progress reports by the required deadlines may result in the suspension or revocation of ethics approval. Researchers are advised to review their approval conditions regularly to ensure compliance with reporting requirements.

4.5.2 Final reports

A final report is required upon completion of the Research or when ethics approval expires, whichever occurs first. The report must:

- summarise the project's outcomes and key findings;
- describe any ethical issues encountered during the project; and
- confirm the status of any remaining obligations, such as data disposal.

Failure to submit a final report may delay approval for future projects or trigger additional monitoring actions by the University.

4.5.3 Monitoring activities

The University or UniSQ HREC conducts monitoring activities to verify compliance with approved protocols and ethical standards. Monitoring may include:

- inspections of Research sites, data storage systems, or participant consent

documentation;

- reviews of submitted milestone reports; and
- collection of feedback from Research participants through interviews or other mechanisms.

Monitoring activities are determined by the project's Risk classification, scope, and complexity. Researchers are expected to cooperate fully with all monitoring activities and to provide access to relevant documentation as requested.

Failure to submit reports or comply with monitoring requirements may result in the suspension or revocation of ethics approval until the identified issues are resolved.

4.5.4 Clinical trials

The UniSQ HREC is responsible for overseeing the progress of clinical trials to ensure they are conducted, recorded, and reported in accordance with:

- the approved protocol;
- standard operating procedures (SOPs);
- good clinical practice (GCP); and
- applicable regulatory requirements.

Where the nature of a clinical trial warrants additional oversight, the University, in consultation with the UniSQ HREC, may establish and operate a Data Safety Monitoring Board (DSMB). This process will be conducted in alignment with the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods and the supplementary guidance on Data Safety Monitoring Boards.

The DSMB, if established, will provide an additional layer of monitoring, particularly for trials involving therapeutic goods, to safeguard participants and ensure data reliability.

4.6 Adverse events

Adverse events are unforeseen incidents that may increase the Risk of harm—physical, psychological, social, economic, or legal—to participants, Researchers, or other stakeholders during Research. These events must be promptly reported to the UniSQ HREC to safeguard participant welfare, uphold Research integrity, and ensure appropriate mitigation actions.

Researchers must take immediate action, including:

- ceasing data collection and securing all data;
- safeguarding participants and stabilising the Research environment; and
- reporting the incident to the Research Integrity and Ethics Team by submitting an adverse event report via the Research information management system, usually within 48 hours. A detailed summary of the event and the immediate actions taken to mitigate Risks should be included.

For incidents within a University facility, Researchers must also report in accordance with the University's Work Health and Safety Policy.

The Research Integrity and Ethics Team will assess the report and may take actions such as requesting modifications to the ethics approval, suspending the ethics approval, recommending additional safeguards to prevent recurrence, or other actions determined in consultation with the UniSQ HREC.

4.7 Suspension or discontinuation of Research

Research projects may face suspension or discontinuation if ethical standards are not met or participant welfare is at Risk. Ethics approval for a project may be suspended or discontinued by the University or the UniSQ HREC under the following circumstances:

- the welfare of participants is at Risk;
- as the Research progresses, its continuation would disadvantage some of the participants as determined by the Researchers or others monitoring the Research;
- Researchers fail to comply with the conditions of approval; or
- the Research is not being conducted in accordance with the approved protocol.

If a suspension or discontinuation occurs:

- the Researcher, collaborating institutions, funding bodies and, where possible, participants will be informed;
- the Research will be promptly halted and arrangements made to meet any resulting needs of participants and collaborating institutions; and
- the Research will not be continued or resumed until any outstanding conditions have been met and continuation is approved by the relevant ethical review body.

Suspension or discontinuation may lead to additional requirements for resumption of the Research or permanent termination.

4.8 Record-keeping

Records will be maintained in accordance with the University's Records Information and Management Policy and the Management of Data and Information in Research: A guide supporting the Australian Code of the Responsible Conduct of Research. 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 records 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@unisq.edu.au, and in accordance with the University's Policies on record-keeping.

Researchers must keep an auditable record of the Research that has been approved (or exempted from ethics review) including, but not limited to:

- Research data (original and analysed);
- a Research data management plan;
- ethics approval or exemption from ethics 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.

4.9 Management of Complaints

4.9.1 Complaints about Researchers or the conduct of Research

Concerns and Complaints regarding the ethical conduct of UniSQ Research should be made in writing via email to the Senior Manager (Research Integrity and Ethics) at researchintegrity@unisq.edu.au.

Researchers are encouraged to self-disclose potential breaches of their Human Research ethics approval and/or the National Statement.

The UniSQ HREC Chair will consider Complaints about the conduct of an approved Research project in the first instance. If a Complaint includes allegations relating to Research conduct, it will be managed in accordance with the University's Research Code of Conduct Policy and Research Code of Conduct: Management of Potential Breaches Procedure.

4.9.2 Complaints about the conduct of the UniSQ HREC or reviewers

Concerns and Complaints regarding the UniSQ HREC or its review processes should be made in writing via email to the Senior Manager (Research Integrity and Ethics) at researchintegrity@unisq.edu.au, to be provided to the UniSQ HREC Chair. Details for the grounds of the Complaint and the name and contact details of the Complainant should be included.

The UniSQ HREC Chair will consider Complaints and make a recommendation based on the evidence provided. If a resolution cannot be reached through communication between the Complainant and the HREC, the Office of Research may consider the Complaint, seeking further advice internally or externally as appropriate.

4.10 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. Potential breaches are managed in accordance with the Research Code of Conduct: Management of Potential Breaches Procedure.

5 References

National Health and Medical Research Council, Australian Research Council and Universities Australia (2025). National Statement on Ethical Conduct in Human Research. Canberra: National Health and Medical Research Council.

6 Schedules

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

7 Procedure Information

Accountable Officer	Deputy Vice-Chancellor (Academic and Research)
Responsible Officer	Director (Office of Research)
Policy Type	University Procedure
Policy Suite	Research Code of Conduct Policy
Subordinate Schedules	
Approved Date	9/10/2025
Effective Date	9/10/2025
Review Date	2/1/2031
Relevant Legislation	*Privacy Act 1998* (Cwth) *Information Privacy Act 2009* (Qld)
Policy Exceptions	Policy Exceptions Register
Related Policies	Code of Conduct Policy Marketing and Brand Policy Records and Information Management Policy Research Policy Student Grievance Resolution Policy Work Health and Safety Policy
Related Procedures	Authorship Procedure Research Code of Conduct: Management of Potential Breaches Procedure

	Research Data and Primary Materials Management Procedure Research Management Procedure Website 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 AIATSIS Code of Ethics Keeping research on track II 2018 National Health and Medical Research Council (NHMRC) NHMRC supplementary guidance on Data Safety Monitoring Boards National Statement on Ethical Conduct in Human Research (2025) Safety monitoring and reporting in clinical trials involving therapeutic goods UniSQ Human Research ethics application forms and resources
Definitions	**Terms defined in the Definitions Dictionary**
	Complainant A person who has made a Complaint. Complaint A Complaint is an “expression of dissatisfaction made to or about the University, related to its products, services, staff or the handling of a complaint, where a response or resolution is explicitly or implicitly expected or legally required”. 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.

Higher Degree by Research (HDR) Student

A Student enrolled in an HDR program.

Human Research

Human Research is conducted with or about people, or their data or biospecimens. 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 biological material as defined by the National Statement on Ethical Conduct in Human Research (2025); access to their individual information in identifiable or potentially re-identifiable form as included in an unpublished source or database that is used for human research.

Policy

A high level strategic directive that establishes a principle based approach on a subject. Policy is operationalised through Procedures that give instructions and set out processes to implement a Policy.

Procedure

An operational instruction that sets out the process to operationalise a Policy.

Research

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

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. Risk The effect of uncertainty on objectives. 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.
	Definitions that relate to this procedure only
Keywords	ethics, human, research, review
Record No	18/1191PL