

University of Tasmania Human Research Ethics Committee

Working Procedures

Responsible Officer	Manager – Research Ethics Unit
Approved by	Deputy Vice-Chancellor (Research)
Review by	September 2026
Relevant Legislation, Ordinance, Rule, and/or Governance Level Principle	<ul style="list-style-type: none"> • Research Policy • Research Ethics Procedure • Research Integrity Complaints Procedure • NHMRC National Statement on Ethical Conduct in Human Research 2023
Responsible Organisational Unit	Research Ethics Unit

Contents

1.	Guidance to Researchers.....	2
2.	Research Exempt from Ethics Review.....	2
3.	Submission of Applications for University HREC Review.....	3
4.	Preparation of Agendas and Minutes	4
5.	Frequency of Meetings	4
6.	Attendance at Meetings.....	4
7.	Conflicts of Interest	5
8.	Responsibilities of University HREC Chairs/Committee Members.....	5
9.	Timely Consideration and Review of Research Proposals.....	5
10.	Conduct of Meetings.....	5
11.	Decision making.....	6
12.	Notification of Decisions.....	6
13.	Monitoring of Approved Projects	7
14.	Complaints / Concerns	7
15.	Withdrawal / Suspension of Ethics Approval	8
16.	Record Keeping	8
17.	HREC Reporting.....	9
18.	Ethics Review Fees	9
19.	Amendment to Working Procedures	9
20.	Glossary	9
21.	Versioning.....	9

1. Guidance to Researchers

1.1. The University Human Research Ethics Committee (University HREC) will assist researchers to meet ethics requirements with the provision of resources necessary to design ethically sound research and effectively navigate the ethics process. University Staff and Students have access to a broad range of resources via the University Intranet.

- Mylo Unit – Human Research Ethics at the University of Tasmania (Ethics101)
- Decision Support Tool – to assist in determining whether a research project requires ethics approval.
- Principles and Elements of Human Research Ethics Tool
- Templates and Resources; including protocol/project description and participant information sheet and consent form templates.
- FAQs
- Guidance on managing ethics approvals
- References to University of Tasmania policies / procedures

1.2. Researchers external to the University also have access to a range of support tools and information via the University Internet pages for Human Ethics.

2. Research Exempt from Ethics Review

2.1. Some research may be eligible for exemption from ethics review.

2.2. The University HREC acknowledges that most in-class teaching activities in which data are gathered for demonstration or assessment purposes and not the intent to generate novel knowledge, are typically not considered research under these working procedures. If, in addition to the purpose not being the generation of novel knowledge, data are not retained by the educator, and no production of external outputs occurs, then for most cases the activity does not meet the criteria for human research. Teaching activities which meet all four of the following criteria are typically not considered research under these working procedures and do not require the submission of an ethics application or HREC Grant of Exemption Request.

- a) No novel knowledge will be generated
- b) Data will not be retained
- c) Data will not result in any external publication or publicity; and
- d) All data is generated or collected from University of Tasmania Staff and/or Students.

Activities which meet all four of these criteria fall under the remit of the relevant University of Tasmania Learning and Teaching Committee with relevant oversight of the Units and/or Courses in which these activities occur. If uncertain about whether a particular in-class teaching activity meets these criteria or may require an ethics application, University staff/students are encouraged to contact the University HREC at human.ethics@utas.edu.au. The University HREC also notes University staff/students may find value in consulting with the applicable Learning and Teaching Committee, and/or the Associate Head Learning and Teaching for the associated School/Discipline about any in-class activities if uncertain of whether it is a research activity.

Examples of activities which would not require an ethics approval or a HREC grant of exemption requests include:

- Asking class members to engage in multiple choice questions to assess learning.
 - Asking for the opinions of the class on specific topics in interactive exercises and discussions.
 - Straw polls in class to gauge learning or understanding of concepts whether undertaken physically or digitally (provided data are not retained by the educator).
 - Asking students to debate/litigate arguments in class.
 - Generating fictional datasets or class datasets for an assignment or assessment task which will not advance knowledge of the field/discipline (e.g., by replicating a well-known theory or study to demonstrate its effects to a class).
- 2.3. Having students analyse existing public data for a class exercise or assignment which will not result in any public facing document (i.e., solely for the purposes of class demonstration or assessment).
- 2.4. The decision as to whether to grant an exemption from ethics review for a research project is the responsibility of the University HREC, it is not the responsibility of the researcher.
- 2.5. Research eligible for a grant of exemption must be lower risk research, not involve a waiver of consent for the use of personal information and satisfy one or more of the conditions set out in the National Statement on Ethical Conduct in Human Research 2023 (the National Statement).

Examples of research activities which would fall under the remit of a HREC grant of exemption request include:

- Collecting data from students with the intention of engaging in citizen science resulting in publications or other public-facing documents.
 - Collecting data from students for a class project which will result in a publicly available podcast/interview/conversation piece.
- 2.6. Collecting data from students across years for the purpose of comparing trends over time across different years and classes

3. Submission of Applications for University HREC Review

3.1. The University HREC has adopted the following risk profiles in accordance with the National Statement:

Lower Risk Research	Higher Risk Research
No risk of harm or discomfort; potential for minor burden or inconvenience or No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)

- 3.2. Researchers are required to submit their applications, and all required supporting documents, via the University online ethics platform.
- 3.3. Lower risk projects, as per national guidelines, can be reviewed out of session by the University HREC Chair/Deputy Chair unless certain aspects of the research require Committee review.

- 3.4. Higher risk applications, as per national guidelines, must be reviewed by the University HREC.
- 3.5. The University HREC may also review applications for research conducted in Tasmania by institutions other than the University in cases where the research strategically aligns with the University and the Committee has the expertise and capability.
- 3.6. The University HREC does not accept ethical approvals from other countries.

4. Preparation of Agendas and Minutes

4.1. The Research Ethics Unit (REU) is responsible for the preparation and distribution of the Committee agenda. Following the internal closing date for submissions, the REU will prepare an agenda for the meeting, which should include:

- Apologies
- Minutes of the previous meeting for HREC endorsement
- Details of where to access items for review
- Other matters for HREC discussion
- Information and items of interest
- Provision for members to raise Other Business

4.2. The agenda and items for review will be available via the University online ethics platform and sent to committee members on the Tuesday or Wednesday prior to the meeting held the following week on Monday or Tuesday, respectively.

4.3. The REU is responsible for the preparation and distribution of the Committee minutes/outcomes. Following the meeting, the REU will:

- Collate the comments on each submission in consultation with the University HREC Chair
- Record the HREC decision within the University online ethics platform
- Prepare the minutes document, which includes the outcome of each submission
- Circulate the minutes document to committee members

4.4. The University HREC Chair/Deputy Chair is responsible for endorsement of the minutes prior to the notification of outcomes to the researcher(s) via the University online ethics platform.

5. Frequency of Meetings

5.1. The University HREC meets on a weekly basis, meeting dates and submission deadlines are publicly available on the University Intranet. To assist researchers with their planning, time periods where meetings will not be held will be published on the University Intranet.

6. Attendance at Meetings

6.1. In adherence with the national guidelines, the minimum membership of eight across the prescribed categories must be represented at every meeting, either in person or having reviewed the submissions and provided comments via the University online ethics platform prior to the meeting. The University HREC Chair/Deputy Chair must ensure that comments from absent members are read and discussed at the meeting.

- 6.2. The University may appoint members who are additional to the eight minimum members. These members may represent minimum membership categories or have experience/expertise relevant to the work of the Committee.
- 6.3. In some circumstances, the Committee may seek advice from experts (Expert Reviewer) to assist with consideration of an application, provided they have no conflicts of interest in relation to the proposal under consideration. Expert Reviewers are required to sign a University Confidentiality Agreement.
- 6.4. Observers of meetings are permissible for new members recruitment. Observers will be required to sign a University Confidentiality Agreement.

7. Conflicts of Interest

- 7.1. At the start of each meeting, it is the responsibility of the University HREC Chair/Deputy Chair to ask members if they have a conflict of interest to declare. Committee members must declare any real or potential conflicts of interest.
- 7.2. No member of the Committee shall adjudicate research in which that member has an interest, including personal involvement, financial interest or involvement in competing research.
- 7.3. The University HREC Chair/Deputy Chair will determine whether the committee member who declares a conflict of interest with an agenda item should leave the meeting or remain present during discussion. A committee member who is listed on a proposal considered by the Committee must leave the meeting during discussion and decision-making on their application.

8. Responsibilities of University HREC Chairs/Committee Members

- 8.1. Each Committee member is responsible for deciding whether, in their judgement, a research proposal meets the requirements of the National Statement and other relevant guidelines and is ethically acceptable.
- 8.2. To fulfill that responsibility, each Committee member should meet the requirements outlined in section 5.2.22 of the National Statement.

9. Timely Consideration and Review of Research Proposals

- 9.1. Applications and other types of submissions that require University HREC review will only be considered at scheduled meetings of the Committee.
- 9.2. All other submissions will be reviewed in a timely manner out of session by a University HREC delegate.
- 9.3. The University HREC is committed to ensuring applications and other submissions are reviewed in a timely manner and that any outcomes or decisions are communicated to the relevant project stakeholders as soon as possible.

10. Conduct of Meetings

- 10.1. Meetings are held online via the University Zoom.
- 10.2. Committee Members are required to review agenda items prior to the meeting and provide any comments against the submission within the University online ethics platform.

10.3. The University HREC Chair/Deputy Chair is responsible for opening the meeting, facilitating discussion and keeping the conversation focused and balanced. The University HREC Chair/Deputy Chair ensures every member feels confident and safe to share their views and that all comments on the application are reviewed/discussed at the meeting.

10.4. Decisions by the University HREC about whether a research proposal meets the requirements of the National Statement are informed by an exchange of opinions from all members of the Committee participating in the meeting.

10.5. The University HREC is tasked with reaching decisions by general agreement or consensus.

11. Decision making

11.1. The University HREC delegates some of its responsibilities to the Chair, Deputy Chairs and REU Executive Officers.

11.2. As required by the National Statement, all committee members will be offered equal time for discussion and have an opportunity to contribute their views in the decision-making process on each submission. Deliberations of the Committee are confidential.

11.3. If the committee members cannot reach a consensus, the meeting chair will make the final decision.

11.4. The University HREC may approve, request modification of, reject or withdraw approval of a research proposal.

11.5. The University HREC will evaluate each submission using the following review categories:

- **Approved**
- **Revision Required** – the researcher must address the comments raised by the University HREC/Delegate and resubmit for further review. The University HREC/Delegate will determine the review pathway: back to Committee, back to HREC Chair/Deputy Chair, back to Executive Officer.
- **Not Approved** – the submission has been rejected by the HREC without the option of resubmitting. In this case, the University HREC/Delegate will provide the research team with reasons for the decision and additional guidance.

12. Notification of Decisions

12.1. Communication between the researchers, the REU and the University HREC is primarily via email and the University online ethics platform.

12.2. The University HREC Chair/Deputy Chair may consider holding face-to-face meetings with researchers to resolve issues about research proposals that may be difficult to resolve through other means. In some circumstances, the Committee may invite researchers to be present at a meeting for presentation and discussion of their application.

12.3. Decisions/outcomes from the University HREC are communicated via the University online ethics platform to the researcher(s) within five working days. Comments and recommendations which need addressing for each submission are also provided to the researcher within the University online ethics platform against the section of the application which may need addressing in support of the Committee feedback.

12.4. When ethics approval is granted, the REU will supply an official approval letter outlining the title of the research, approval date, a list of approved documents and any conditions contingent on the approval.

12.5. Researchers may contact the REU for further information or clarification of HREC decisions.

12.6. Researchers can dispute any University HREC decisions with sufficient justification by contacting the REU.

13. Monitoring of Approved Projects

13.1. The University HREC is responsible for monitoring research for which it has given approval. In doing so it may request and discuss information on any relevant aspects of the project with the researcher at any time.

13.2. Ethics approval is granted for four years contingent upon the receipt of annual progress reports.

13.3. Extension reports for the continuation of ethics approval can be submitted on the fourth year of the study and are approved on a case-by-case basis.

13.4. A final report is required to close the project and the ethics approval of the study.

13.5. As a condition of approval, researchers must immediately report anything which might warrant review of ethical approval of the application, including:

- Any deviations from the approved Protocol/Project Description
- Any unforeseen events that might affect continued ethical acceptability of the project
- Any information which may have an impact upon the continued ethical acceptability of the project

13.6. The University HREC requires the following information in an annual report:

- Progress to date (including publications and presentations)
- Compliance with the approved Protocol/Project Description
- Assurance of data maintenance and security of records
- Any adverse events
- Any ethical issues
- Any complaints relating to the project

13.7. Continuation of ethics approval for clinical trial research is contingent upon the adherence with safety monitoring arrangements as indicated in the NHMRC guidance and with the manner and form specified by the University HREC.

13.8. The University HREC may recommend and/or adopt additional mechanisms for monitoring at its discretion.

13.9. All reporting submissions to the University HREC is required via the online ethics platform.

14. Complaints / Concerns

14.1. Complaints / concerns about the conduct of a study may be raised by anyone, including, and not limited to:

- Potential participants or participants in the research
- Members of the University

- Members of the community

14.2. Complaints / concerns from researchers about the consideration of research applications by the University HREC, or other aspects of Committee business, should be raised in the first instance with the REU.

14.3. In accordance with the *National Statement on Ethical Conduct in Human Research (2023)*, contact details for the REU as the recipient of complaints / concerns for ethically approved research will be provided to all participants in research involving humans.

14.4. All Concerns / complaints about the conduct of a study or the functioning of the HREC will be managed in accordance with the [Research Integrity Complaints Procedure](#).

15. Withdrawal / Suspension of Ethics Approval

15.1. If for any reason the University HREC has reason to believe that continuance of a research project will compromise participants' welfare or if the conditions of ethics approval for the project (including reporting requirements) are not being adhered to, it will immediately seek to establish whether ethics approval and / or authorisation for the project should be suspended or withdrawn.

15.2. The University HREC will inform the research team and where applicable the project Sponsor of the withdrawal / suspension of the project and any actions / conditions.

15.3. In some cases, the instruction to cease any research activities due to withdrawal / suspension of a research project will come from the Deputy Vice Chancellor Research (DVCR).

15.4. Research activities must be halted if ethical approval has been withdrawn / suspended.

15.5. Where ethics approval for a research project is withdrawn / suspended, continuation of the research project is subject to re-application and re-approval by the University HREC.

16. Record Keeping

16.1. The University online ethics platform contains details of each application to conduct research with human participants, which includes and is not limited to:

- Project identification number
- Title of project
- Name and contact details of the Chief Investigator
- Name and contact details of the research team
- Institutions of the research team
- HREC and/or reviewer comments
- HREC and/or reviewer decision
- Starting date and anticipated completion date for the research project
- Relevance of Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information
- Meeting at which the submission was considered, if reviewed by Committee
- Name of reviewers, if not reviewed by Committee
- Date of submissions
- Date of revision requests
- Date of approval
- Copies of approval letters and notifications
- Copies of approved project documents
- Due dates of annual reports
- Other details as required

17. HREC Reporting

17.1. The University HREC will provide an annual report as required to the NHMRC on matters specified in the National Statement on Ethical Conduct in Human Research. The University HREC will provide other information to the NHMRC on request.

17.2. The NHMRC HREC yearly report is also, as per the Terms of References, the University HREC annual report on its operations to the Deputy Vice Chancellor Research (DVCR).

18. Ethics Review Fees – External Applications

18.1. Applications submitted by external researchers and industry are subject to a fee-for-service.

18.2. Invoices are processed by the REU monthly for the applications and amendments received the month previous.

18.3. The [fee schedule](#) is published on the University website.

19. Amendment to Working Procedures

19.1. Amendments to this document must be approved by the DVCR and must not affect compliance with the National Statement on Ethical Conduct in Human Research.

19.2. The REU will maintain records of amendments and the date of each amendment.

20. Glossary

DVCR	Deputy Vice Chancellor (Research)
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
NHMRC	National Health & Medical Research Council
REU	Research Ethics Unit

21. Versioning

These working procedures shall be reviewed every two years.

Current Version	Version 1 – University of Tasmania Human Research Ethics Committee – Working Procedures – September 2024
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