

Human Research Ethics HREC Overview and Application Process



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Research projects involving human research

The National Health and Medical Research Council (NHMRC) mandates that all research projects involving human participants - including surveys, interviews, qualitative research, and observation - are to be reviewed and approved before commencing. The *National Statement on Ethical Conduct in Human Research (2018) (National Statement)* applies to 'any researcher conducting research with human participants; any member of an ethics review body reviewing that research; those involved in research governance; and potential research participants'.

The *National Statement* is available on the [NHMRC website](#) and on the University of Divinity [HREC webpage](#). You should consult the National Statement when completing the relevant University of Divinity Application for Ethics Approval of a Research Project. The National Statement sets out the general principles on which your application will be considered. The purpose of the National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

You should also consult the [Australian Code for the Responsible Conduct of Research](#) and, where relevant, the document [Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research](#).

The University of Divinity has an HREC Policy and is required to have an active Human Research Ethics Committee (HREC). The Terms of Reference of the HREC are governed by Regulation 1 of the University of Divinity.

The HREC Policy, this Overview, and other HREC documents apply to all research conducted by University of Divinity staff and students, including honorary researchers.

HREC must be notified of all research involving humans, and applicants must receive Ethics Approval from HREC before commencing research.

The likely benefit of the research must justify any risks of harm or discomfort to participants. In order to gain ethics approval a research project must demonstrate it is minimising or managing the risk of physical, mental and spiritual harm by the research and its procedures. The ethics approval process also aims to protect the welfare of the researcher and their rights to carry out legitimate, justifiable investigation. It establishes a framework of accountability. It seeks to avoid the risk of any claims of negligence being made against the researcher, or the University.

Research projects that may not need HREC approval

There are some exceptions to the requirement that all research projects involving people need to be approved by HREC. Such projects may include:

1. Undergraduate projects with an education, training, or a practical experience focus. These do not normally require approval. Student coursework, assignments and essays are also exempt.

2. Use of information freely available in the public domain.
3. Research about a living individual involved in the public arena where the research is based exclusively on publicly available information, documents, records, works, performances, public archives or third-party interviews (while complying with relevant copyright, permissions, and intellectual property requirements).
4. Studies of public behaviour that are purely observational (non-invasive and non-interactive), such as standing in a public place and noting the actions of passers-by. However Ethics Approval by HREC is required if the disclosure of recorded observations identifies individuals (names, photographs) or places them at risk of harm, stigma or prosecution.
5. Purely observational studies (with no element of intervention) in established educational settings, involving normal educational practices, researching current instructional strategies, or research on the effectiveness of instructional techniques, curricula, or classroom management. In studies such as these, appropriate permissions are required.
6. Testing within normal educational requirements and in accordance with a host institution's normal practices and approvals.
7. Quality assurance/audit projects that do not involve access to or collection of private, sensitive, or health data. Sensitive data is defined in the *UD Privacy Policy* and Australian law as "information or opinion about an individual's racial or ethnic origin, political opinions, membership of a political association, religious beliefs or affiliations, philosophical beliefs, membership of a professional or trade association, membership of a trade union, sexual preferences or practices, or criminal record that is also personal information."
8. Education, training and practical classes among students, which do not involve students learning through testing procedures on each other.

Research projects that must have HREC Ethics Approval

'Human research' has a broad definition and includes research conducted with or about people, or their data. You need Ethics Approval if you are a University staff member or a postgraduate student (including Minor Thesis) or an honorary researcher and wish to conduct certain research activities involving humans. These include, but are not restricted to, any one of:

1. Gathering information about human beings (and organisations) through interviewing, surveying, questionnaires, observation of human behaviour, audio/video taping, administering tests or stimuli.
2. Where the research is being funded by an organisation external to the University, or where such funding has been sought.
3. Where there is a risk of physical, mental, social, spiritual or other harm.

Such risks may arise if the project involves surveys, interviews, or focus groups which could reasonably result in placing a subject/participant/interviewee at risk of criminal or civil liability, damage to his/her financial, reputation or social standing and employability, or cause discomfort, or distress.

4. Where the research involves possible breaches of legislative confidentiality.

Ethics Approval by HREC is required by law for any research project which involves access to existing records of personal information about subject(s) held by a public or private organisation, agency or individual, where (any of these):

- a) the information is not publicly available
- b) the data has been recorded in such a way that subject(s) can be identified directly or through identifiers linked to the subject(s), and
- c) the disclosure of which requires obtaining the consent of the subject(s).

5. Study or research in illegal activities.

Informed Consent

All research involving humans must proceed on the basis of their ***informed consent***. Every person involved in such research must be provided with all the relevant information they need to make an informed decision whether or not to participate, without coercion or inducement. If a research project involves children (under 18), people in special groups such as prisoners, or people of diminished capacity, informed consent must be obtained from a parent or guardian.

Research Project Design

All research proposals must be designed to ensure that any risks of inconvenience, discomfort or harm to participants are balanced by the likely benefit to be gained. (*National Statement* p.13ff.)

You must *suspend or modify* any research in which the risks to participants have changed from the HREC approved research project, and stop any involvement of any participant who is having their welfare compromised or negatively affected in an unforeseen way. You are required to advise HREC immediately.

Further Advice

Any researcher who is uncertain whether their research project requires approval from the HREC must seek advice from the University's [HREC Coordinator](#).

Before Applying

Understand the principles of Human Research Ethics and also the details of the information you must provide in the HREC Application in order to assist you in the design of your research project.

Every research project that is submitted to HREC must first have been endorsed by an approval process (Minor Thesis), approval or Confirmation panel (HDR), or College-based or the University's School of Graduate Research peer-review (staff or Honorary researchers).

Can my Application be Expedited?

At a minimum, if any of your participants:

- Are not 18 years or older
- Are not in a state of sound health or capacity (this means any physical or mental illness, disability or impairment that may affect the participant's ability to consent to, understand, or participate in the research)

- Do belong to a vulnerable cultural group (this means you are deliberately selecting members of a culturally or ethnically vulnerable group, including Aboriginal and Torres Strait Islanders and those detailed in section 4 of the National Statement)
- Are women who are pregnant (this means you are deliberately selecting women who are pregnant)
- May suffer a foreseeable level of harm (harm means 'beyond discomfort or inconvenience'. See National Statement Section 2 for guidance on assessing harm to participants, including the levels of likelihood and of potential severity)
- Will be subject to disguised or covert practises (this means observation, recording, or any other practise done without consent)
- Will be subject to counselling/psychological practices (this means practices, interventions or treatments usually performed by qualified practitioners)
- Will be subject to physical stimulus
- Are subject to any other higher risks

Then your application must be a Full Application. If you believe your project is not subject to high risks, or it has been granted prior approval by another registered HREC, you may apply for your application to be Expedited. The decision on whether to accept an application for expedited processing rests with the Chair of the HREC.

HREC Expedited Applications may be submitted at any time and are assessed on a rolling basis. HREC Full Applications must be lodged by 5pm on the HREC Application closing date, and are assessed at scheduled meetings of the HREC.

Applying for Approval from the Human Research Ethics Committee

1. Download and read the HREC Overview and HREC Additional Documents Guide, available on the University's HREC webpage.
2. Complete the HREC Application Form available on the University's HREC webpage. The form is dynamic and will allow you to request an Expedited Application.
3. Due dates are available on the University's HREC webpage. Late applications will not be accepted.
4. You may be invited to an short interview at the following HREC meeting (Full Applications only.)
5. An application in which ethics approval is sought for a proposed research project is assessed as set out in the University's HREC Policy. The HREC makes one of the following decisions:
 - a) to exempt the project from requiring ethics approval
 - b) to grant ethics approval
 - c) to grant ethics approval subject to minor changes or clarification
 - d) not to approve the application, but require it be revised and resubmitted to HREC
 - e) to reject the application.

Where changes and/or a resubmission are required, the Chair of the HREC or the HREC Coordinator communicates the nature and extent of the changes to be made.

Enquiries about the outcome of an HREC meeting must be made only through the HREC Coordinator (or if needed through the Office of the Vice-Chancellor.)

Appeals and Complaints

An applicant who wishes to request a review of a decision regarding an application for HREC Approval should consult the University of Divinity HREC Policy and submit a Review Request Form. Researchers who believe they have grounds for an appeal or a complaint should refer to the University's [Appeals and Complaints](#) webpage. Complaints from participants in a research project are to be made in writing to the HREC Coordinator.

Changes, Unforeseen Events, Harm to Participants

The *National Statement* requires the researcher to contact the University of Divinity if any of the following situations arise or are likely to arise (at any stage in their project):

1. substantial changes to the research project, questionnaire, or interview outline.
2. unforeseen events that might affect the continued ethical acceptability of the research project. In such circumstances, the researcher must postpone any further research until the HREC has determined the most appropriate way of addressing the situation.
3. participants having their welfare compromised or negatively affected in an unforeseen way. In such circumstances, the researcher must **immediately cease** the research until the HREC has determined the most appropriate way of addressing the situation.

Further Information

For more information see the text and downloadable documents on the University of Divinity [HREC webpage](#). For any queries, contact the [HREC Coordinator](#).