

# Frequently Asked Questions

## *CDU Human Research Ethics*

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## Do I need Human Research Ethics Clearance?

The National Statement (NS) defines which activities are considered to be human research (under *Purpose, scope and limits of this document*) and establishes that all such activities require ethical review except where institutions determine that they are eligible for exemption (see NS 5.1.22).

The scope of human research includes all disciplines where the work includes:

- interviews, surveys or focus groups;
- observations (participant and non-participant);
- online data collection from individuals (including social media and forum comments);
- testing; and
- clinical interventions, innovations and trials.

This also includes the analysis or other research use of identified personal information that is not already on the public record. For example, comments published in the academic, professional or popular press.

Some quality assurance/evaluation/teaching activities may not require ethical review (see more FAQ's below). Even though such activity does not need to undergo ethical review, the design and conduct of that work must adhere to ethical principles and standards.

## How do I apply for Human Research Ethics clearance?

Learn more about the [proposal approval process](#) at CDU

Completed applications for CDU-HREC must include all required signatures and documents (see checklist). If your application needs to be reviewed by the full committee, it will need to be received before the submission deadline. Late submissions will not be considered until the following meeting date. Proposals eligible to be considered via the Executive Review Pathway are reviewed on a rolling basis outside of the CDU-HREC meeting submission dates. See [Submission of new proposals for more info.](#)

Your proposal should be submitted electronically via email to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au). The submission should include the electronic form and any required attachments. All signees must be copied into the submission email. If you have any trouble submitting, contact the Research Ethics Coordinator ahead of the submission date.

**Please note:** You will need Adobe Acrobat Reader to view pdf files. Get [Adobe Acrobat reader](#). upgrade to XI if possible.

## **How do I know which form to fill out for my ethics proposal and where should I then submit this?**

There is only one standard human research ethics form, which is available on the Human Research Ethics website. Once completed, submit this to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au).

*CDU students undertaking a masters by coursework with a research component, an honours or undergraduate student project*, may have their projects covered under Program Ethics Approval held by the unit or course coordinator.

*If you are a Menzies student or a CDU student undertaking research using NT Department of Health resources or Menzies resources*, you must apply through the Menzies School of Health Research. Visit the Menzies Ethics website for further information. Where such applications involve CDU staff, students and/or facilities, the applicant needs to submit a copy of the clearance notice (once granted by the NT Department of Health and Menzies School of Health Research HREC) along with a copy of the approved application and any attachments to the CDU-HREC, as per the reciprocal application process outlined on the Human research ethics webpage.

## **When do I need to seek reciprocal approval?**

It is University policy that all research involving human subjects must be approved and monitored by the CDU Human Research Ethics Committee. All CDU researchers (employees, honorary appointees or visitors) and research students must obtain approval from the CDU HREC for research involving human subjects.

CDU recognises approvals from other registered ethics committees through the pathway of Reciprocal Approval.

- If you are a CDU researcher or research student named on a protocol first approved by another ethics committee, you must also obtain CDU-HREC approval for your research. In most circumstances this can be provided as a reciprocal approval derived from the original approval.
- Some researchers and research students hold joint positions at CDU and another institution. You must always obtain CDU HRC approval in this case, even if you hold a position at the institution providing the original approval. This may seem unnecessary, but CDU must have a record of your ethics approval in the event of a complaint or expression of concern and your best interests need to be considered.
- If a CDU HDR student joins a project approved at another institution, reciprocal approval must be sought and obtained immediately. This is particularly relevant when a CDU HDR student joins a project that has Top End HREC approval (Menzies), but which has not received reciprocal CDU HREC approval.

The procedure for seeking reciprocal approval is as follows:

Locate and download the CDU ethics proposal (application) form on the Human Research Ethics website. Complete pages 1, 2, and as far as Question 1c on page 3. Then complete questions 15 & 16. Send this electronically with evidence of approval from the approving HREC and including

a copy of the original ethics application and any other relevant documents, for example, consent form, plain language statement/information sheet, questionnaire survey to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au)

This process applies to all CDU staff

## **I want to publish an evaluation/quality assurance project. Will I need clearance?**

If the project is considered to be human research, then an ethics submission will be required. Research is viewed as an 'investigation undertaken to gain knowledge and understanding or to train researchers' (NHMRC National Statement 2018 p6). Research contributes to the knowledge of a specific academic discipline, is aligned with theory and includes Indigenous Knowledges. Evaluation research is distinguished from evaluation/quality assurance or audit type exercises. The NHMRC provides guidelines about evaluation and quality assurance projects. Please refer to the guidelines for details.

The following examples are normally exempt from a need for ethics approval:

- teaching and learning at undergraduate level
- projects with an education, training, or practical experience focus
- required student coursework, assignments and essays
- use of information freely available in the public domain; e.g. research about a living individual involved in the public arena that is based exclusively on information that is publicly available, or documents, records, works, performances, public archives or third-party interviews
- non-invasive and non-interactive observation of public behaviour such as sitting in a public place and noting the actions of the general public. Ethics review is required if the disclosure of recorded observations will identify groups, individuals, names, photographs and puts them at risk of harm, stigma or prosecution
- where there is no aspect of intervention, studies that are purely observational in established educational settings that involve routine/normal educational practices, researching current teaching strategies, or research on the effectiveness of teaching techniques, curricula, or classroom management
- quality assurance/audit projects that do not involve access to or collection of private, sensitive or health data
- education, training and practical classes among students, which do not involve students learning through use of testing procedures on one another
- evaluation surveys of University staff and students, e.g. library services, departments, and including student evaluation of teaching.

## **How do I assess project risk? Is my project eligible for Executive Review?**

A research project that involves foreseeable ethical risks that amount to no more than inconvenience, once any risks have been appropriately managed, is considered negligible risk. The National Statement provides guidance (see Chapter 2.1) regarding risk and also mandates that certain categories of research are reviewed by a full HREC (see Chapter 5.1.6),

The risks in any project need to be justified, well managed and clearly articulated to participants. The research team and authorising officer must assess the project risk and make a declaration around this assessment via the CDU-HREC Human Research Ethics Proposal Form. Projects identified as negligible risk may be considered via the Executive Review Pathway and can be submitted at any time to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au).

### **Is there any other documentation I need to submit with my ethics proposal?**

The human research ethics webpage has a checklist and further information about essential documents that form part of your complete submission. All projects usually require a Information Sheet for Participants, an Informed Consent Form), a research agreement for First Nation Research (ATSIRA) and relevant letters of support e.g. from industry. If applying for Reciprocal Approval, evidence of ethics clearance from an Australian NHMRC registered HREC and the complete original application is required.

Any documentation that is to go to the public should be carefully proof read and edited and should have the appropriate institutional branding and contact details listed.

For further information please refer to the example forms and guidance available on our main page. For information regarding CDU and cross-institutional branding please contact the [Office of Marketing & Planning](#):

### **When should I apply for ethics approval and for how long is ethics approval granted?**

Ethics approval timeframes can vary depending on the design of the project and associated risks. You should look into the ethics application process well ahead of submitting an ethics proposal in order to incorporate ethical considerations into the design of your research. Data collection cannot commence until ethics clearance is granted so this needs to be factored into your research timeline. The possibility that further information/clarification about your application may be requested should also be considered.

HDR students must wait until they have received approval from their Confirmation of Candidature (COC) before an application is submitted by their research supervisor. This ensures that the research proposal under ethics review is the final version of the intended research plan.

Ethics clearance is usually granted for the time period requested as long as it is no longer than 5 years (pro-rata for part-time students). Researchers that need to extend their project beyond 5 years will be required to submit a new ethics application. All projects require an annual report to be submitted every year from the date of clearance. If an annual report is not received your clearance will no longer be valid. A final report is required at the completion of the project (or when a project has ceased).

### **My research relates to First Nation Australians. Which guidelines are available?**

- The NHMRC's Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders (2018) replaces the previous *Values and ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research* (2003) and *Guidelines on ethical matters in Aboriginal and Torres Strait Islander health research* (1991).
- *Keeping Research on Track II* (2018), which updates the earlier *Keeping research on track* (2005), provides advice on how the values and principles outlined in Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities can be put into practice in research
- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020) replaces the previous AITSIS Guidelines and GERAIS 2021

### **Can I use social media or a Market Research company to locate participants?**

CDU-HREC will expect that you identify clearly which aspects of social media will be used and how you will address issues of confidentiality, anonymity, privacy and IP. They may also identify specific boundaries, for example, in relation to the use of Facebook.

Provided that using a market research company will not change the nature of your research, CDU-HREC is unlikely to object. Be aware though that you must be able to fund this.

The National Statement on Ethical Conduct on Human Resources provides detailed information. See Chap 3.1 Element 3: Consent: Secondary use of data or information. See below is the link:

[Chapter 3.1 Elements of research](#)

### **What do I need to tell the CDU-HREC about and how?**

The Principal Investigator (PI) is required to report immediately unapproved protocol deviations or protocol violations, that may alter the ethical acceptability of the project, including any:

- Adverse effects of the project on participants and the steps taken to deal with these;
- Other unforeseen events that alter the protocol and
- New information that may invalidate the ethical integrity of the study.

The Principal Investigator must advise the University immediately of his or her inability to continue as PI and advise the name of and contact information for their replacement. The research cannot proceed without an approved PI.

An annual progress report is required prior to each anniversary of the clearance date. Continuation of ethical clearance is contingent on submission of a satisfactory annual progress report. An extension of the project beyond the original expiry date can be requested as long as it does not exceed 5 years from the original date of ethical clearance.

If you are seeking to vary the conditions of your original approved ethics proposal, you need to seek formal approval for the variation. This includes changes to team members if you are leading a research team. For variations that propose addition of team members, please include below declaration:

*We the undersigned confirm that all members of the research team have read this application and the current NHMRC National Statement on Ethical Conduct in Human Research. We accept responsibility for the ethical and appropriate conduct of the protocol detailed in this application, confirm that we will conduct this project in accordance with the principles contained in the National Statement, and confirm that the research team will comply with any other conditions laid down by Charles Darwin University.*

Variations normally encompass minor rather than major changes. An email that clearly identifies the nature of the variation of condition sought and providing a clear, supporting rationale is required. Send this to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au) . Approval (or not) is provided via the Chair of the HREC.

### **Will I be sent a reminder about when my annual report is due**

Reminders for annual reports are sent out several weeks before they're due. If your email address has changed you should inform us via email: [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au). Please remember, continuation of your ethics approval is contingent on the approval of this report.

### **Where can I locate the annual/final report form?**

Through the Office of Research and Innovation website under Annual, renewal and final reports heading : [Research Ethics and Integrity](#).

### **Where can I seek advice about ethical considerations associated with my project?**

If you are an HDR student, you should seek assistance initially from your supervisor, who is the Principal Investigator for your ethics submission. Advice for all researchers in the university can be sought from the Research and Integrity Ethics Team.

### **Who can I speak to about completing the form and submitting an Ethics Proposal?**

Refer to the Human Research Ethics webpage for information and submission and reporting requirements. If you are experiencing difficulties or are unsure of any of the processes, please contact the Research Integrity and Ethics Team: [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au)

### **Are there any workshops or online resources available regarding human research ethics?**

The Office of Research and Innovation provides human research ethics workshops for HDR students through the Enhancement Program and also through individual colleges throughout the year. Workshops can also be provided on request, please contact the Research Integrity and Ethics Team .

Free online human ethics training modules designed for researchers and members of human ethics committees are available at:

[http://mq.edu.au/ethics\\_training/](http://mq.edu.au/ethics_training/)

<http://www.uow.edu.au/research/rso/ethics/human/training/>

There are a number of resources and further information on below, under [Essential Reading](#) and also under the [Research Integrity and Ethics Resources](#) Page.