

# Program Ethics Approvals

Research and Research Training



## Principles for Program Ethics Approvals

Charles Darwin University Human Research Ethics Committee (CDU-HREC)

### What is a Program Ethics Approval?

The University offers projects with an educational, training and/or practical experience investigatory focus in a number of its coursework units or modules (named for example “Research project”, “Research preparation”, “Literature review” and so forth). Where the projects involve human participants in their investigations, these projects may be subject to ethical review at CDU, in accordance with the National Statement on Ethical Conduct in Human Research (National Statement). Program Ethics Review offers a more streamlined way for CDU unit conveners or program coordinators to seek timely ethical approval for a group of student projects covered within a single program of investigations.

### What kinds of investigations can be covered by a Program Ethics Approval?

Program Ethics Approval is available for any program or series of investigations undertaken involving human participants in surveys, interviews, observational studies, data in which individuals are identifiable, tests or stimuli, or the collection or use of human tissue, bone, blood or other body fluids.

### Can we use a single Program Approval for many different student projects?

Yes, the purpose of a Program Approval is to cover multiple investigations in one application including multiple student projects. For coursework or honours programmes the protocols set out in a Program Ethics Approvals will normally support a number and variety of individual student investigations comprising the student(s) and staff member(s) who are members of a particular class for that Unit. Other arrangements for a program are acceptable.

### Can Program Ethics Approval be used for Honours projects or research projects in Masters programs?

Yes, Program Ethics Approvals are designed to allow for a series of projects that utilise similar research designs/methods and which pose the same level of risk to be covered by a single protocol. For Honours or Masters by Coursework projects that do not require a substantial and original research project and where the managed risks are negligible, a Program ethics approval can be utilised. Where a student investigation project is (1) substantial (normally, greater than 40 credit points in total) and (2A) constructed de novo and/or (2B) is likely to lead to an original publication and/or (2C) involves managed risks that are not negligible, a separate application for the ethical review of that project is required.

## Are there any special ethics considerations for research ethics in Program Approvals?

Program Ethics Approvals which cover coursework projects, will generally involve novice students undertaking investigations for the purposes of training and gaining experience. Consistently with the Guidelines of Beneficence, Justice and Respect of the National Statement such coursework projects should involve the minimum possible number of human participants and expose them to negligible ethical risk. The Principle Investigator (PI) on the project must be familiar with the principles and requirements set out in the National Statement at the time of application, and all co-investigators (I.e. the students) are required to be familiar with the National Statement before they commence the investigation.

## How do we prepare and submit a Program Ethics Application?

Applications for Program Ethics Approval are made on the standard CDU ethics application form, submitted through the Research Integrity and ethics Team in ORI, and reviewed in the same way as other human research ethics applications. The application can relate to a module in a unit, an entire unit, a group of units offered in a coursework course or a series of investigations utilising the same methodology.

An application may cover all projects to be undertaken by students in a unit over several years (maximum 5 years). It will explain the nature of potential student projects relating to human participants (including other students), the methods, the recruitment and consent procedures and the specific protocols that are anticipated over the duration of the coursework units in question.

As with all Human Research Ethics protocols, the application will explain how all teaching staff and students in an approved program will confirm in writing that they have read the National Statement and understand the ethical aspects of their specific project. The University will record new students through the normal “variation” procedure for approved projects submitted to the CDU-HREC. Such variation should include declaration statement as below:

*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.*

For every distinct activity under the protocol, an appropriate plain language statement and consent form needs to be created and approved. It is possible to approve templates for the PLS and consent form, with specific changes submitted as variations for each activity as required.

## We would like students to gain experience in preparing an ethics application. How can we do that if the Program Approval is already established?

The CDU Human Research Ethics Committee commends the good practice of requiring all students participating in a unit with a Program Ethics Approval to receive ethics training appropriate to the area of study. Unit learning outcomes might include completing an Ethics Proposal. Proposals prepared by students in these circumstances do not require ethical review by the CDU-HREC. They may be peer reviewed, or reviewed by class teachers or colleagues. The template provided on the CDU-HREC webpage [“Coursework Program Ethics Template”](#) is provided as a resource for such learning experiences.

## Are there any other requirements associated with maintaining a Program Ethics Approval?

As with all CDU-HREC approvals, annual and final reports, incident reports and any request to amend the approval should be submitted to the CDU-HREC. Specific requirements pertaining to Program Ethics Approval reporting are outlined below.

### Program Ethics Reporting Requirements

*These include all variations, annual and final reports.*

#### Variations

For each new researcher or student covered by the Program Ethics Approval, the Principal Investigator (PI) must provide a variation request for CDU-HREC approval that includes:

- (1) the new researcher's, or student's name and qualifications;
- (2) a statement by the PI (as above) that stipulates that:
  - i. the new researcher's, or student's project is fully consistent with the protocol in the program approval;
  - ii. the new researcher, or student has read and understood the program approval protocol;
  - iii. the new researcher, or student has read and understood the National Statement.
- (3) a Plain Language Statement and Consent Form relevant to the project if required or the title and a brief summary of the project.

Variation requests are submitted via email to [ethics@cdu.edu.au](mailto:ethics@cdu.edu.au) and should include the PI and the relevant new researcher or student as confirmation for processing the request. This is to ensure that all new researchers or students are incorporated into the program approval as if their particular protocol is a single instance of the protocol approved under the program approval.

#### Annual/Final Reports

Annual Reports are a mandatory requirement of all HREC approved projects, as set out by the NHMRC guidelines. Where a unit or suite of units has program approval the PI is required to submit a satisfactory annual report to the Research Integrity and Ethics Team ahead of the anniversary of the approval date. A brief summary of each individual student project must be provided in the body of the report identified with the student and project name. Continuing approval is contingent on submission of a satisfactory annual progress report.

The purpose of the annual/final report is to review the implementation, conduct and progress of projects within program approval that identifies and advises the CDU-HREC of any changes. Researchers are required to maintain current clearance for their projects. For continuing units with Program Approval, a final report needs to be submitted at the 5<sup>th</sup> anniversary year of the approval date for review, followed by a renewal application if a new clearance is required.