Section 1 – General Information

These Guidelines should be read in conjunction with the CDU Human Ethics Guidelines and the NHMRC Statement on Ethical Conduct in Research Involving Humans. The Guidelines are available from the CDU Research Office web site at http://www.cdu.edu.au/research/office/apphec.html. The NHMRC Statement is available on the NHMRC Web Site at http://www.nhmrc.gov.au/publications/synopses/e35syn.htm. Both documents are also available from the Executive Officer, Human Research Ethics Committee, Office of Research and Innovation, Orange Building 2, Level 2 Casuarina Campus, ph: (08) 8946 6498.

1. Who must obtain clearance from the CDU Human Ethics Committee?

1.1 Staff and students of CDU

Staff who undertake projects (of a type specified below) involving humans as part of their employment are required to obtain ethics clearance from the Human Research Ethics Committee. CDU staff are all people on the CDU payroll, or individuals affiliated with CDU (eg, adjunct professors) and engaged in projects conducted under CDU’s auspices.

Students who undertake projects as part of their enrolment at CDU are also required to obtain ethical clearance from the Human Research Ethics Committee (HREC).

Staff and students who undertake projects under the auspices of another institution (eg, staff enrolled in a degree at another university) are not required to obtain clearance from the CDU HREC for those projects.

2. Which projects require ethical clearance?

2.1 Research projects involving humans

Research projects which involve humans, either as participants in the research, or as individuals or members of a group upon whom the project may impact, require ethical clearance. Research may be defined in terms of its purpose in establishing facts, principles or knowledge or of obtaining or confirming knowledge.

2.2 Non-research activities involving humans

A number of other activities conducted routinely within a university environment, which have the potential for infringing upon the rights and welfare of individuals also require ethical clearance. Such activities are any which involve the use of instruments used in research and applied to humans and include activities such as quality assurance audits, surveys and tests (other than standard tests for educational purposes).

2.3 Features of projects requiring ethical clearance

Research and other projects which involve humans which have any of the following features, require ethical clearance from the HREC:

- Use of questionnaires, personality tests, interviews, focus group discussions or other means of obtaining information orally or in writing. Surveys can cause emotional distress, may place the participant at risk of criminal or civil liability, or may damage their financial or social standing.
- Investigations of human behaviour, including observation. Even covert observation can have adverse side effects on those observed.
- Accessing of data not directly connected with, but potentially impacting upon, living individuals. Archaeological investigations may have ramifications on the cultural beliefs of living descendants.
- Exploitation of cultural knowledge and/or property, where the use of information has a potential for infringement of privacy or confidentiality of ownership.
- Research involving or impacting upon specific disadvantaged or vulnerable groups, eg, members of ethnic or religious minorities, children, etc. Such research raises ethical issues that deserve special attention, either because they are more complex examples of issues relevant to any participant, or because of the person's condition.
- Experimentation on individuals, whether physical, psychological, or other. Some experiments carry significant risk of harm to participants, either due to the nature of the experiment, or through poor methodology.
- Obtaining bodily samples or other testing of humans. These procedures impact on personal privacy.
• Accessing medical or other personal records, eg, epidemiological research. Accessing such data raises issues of privacy and confidentiality.
• Use of anonymous data records supplied by a third party but where identifying information is obtainable. Access to such data also raises issues of personal privacy and confidentiality.
• Clinical trials or innovative therapy. These procedures raise issues of personal autonomy and significant physical risks may be involved.
• Administration of any substance, eg, drugs, ionising radiation, chemical agents or vaccines. Again, risk of physical harm is involved.

3. Which committee should an application be submitted to?

3.1 Human Research Ethics Committee (HREC)
The HREC is responsible for giving final approval for all applications, although it has delegated some of its initial reviewing responsibilities to Faculty Ethics Committees where faculties have established such Committees. The following projects should be submitted to the HREC:
• Staff research projects,
• PhD and Masters by Research projects
• Where no Faculty Ethics Committee is established, all other projects which would otherwise be submitted to a Faculty Ethics Committee (see below).

3.2 Faculty Ethics Committees (FEC)
FECs review applications and are authorised to give provisional approval which is sufficient to enable a project to commence. The HREC then reviews the decisions of the FEC and will either ratify the decisions or seek (usually minor) changes before ratifying the FEC decision.
The following projects should be reviewed by a FEC:
• Masters by Coursework research component;
• Staff co-ordinating units in which undergraduate students will be undertaking "model" research projects involving humans;
• Undergraduate research projects;
• Graduate Diploma, Honours, and VET student projects;
• Non-research projects undertaken by staff or students.
*Model projects are projects designed by a unit co-ordinator and undertaken by a student or group of students. A selection of model projects may be offered to the class. The unit co-ordinator obtains ethical clearance prior to commencement of the unit, enabling students to commence the project immediately.

The Faculty Ethics Committees have separate guidelines and a briefer application form. To find out if a faculty has a Faculty Ethics Committee and to obtain a copy of the guidelines and form, contact the Faculty Administration Office. The Human Research Ethics Committee Guidelines refer to submissions to the HREC only from this point.

4. What are the steps involved in submitting an application for ethical clearance?

4.1 Be aware of what is required by the HREC and read the relevant policies and guidelines
The CDU Human Ethics Guidelines and these Guidelines should be read carefully before completing the application. Instructions on completing the sections of the application form are included below. It is also highly recommended that the NHMRC Statement be read prior to completing your application, as the HREC must ensure that projects meet the conditions detailed in the NHMRC Statement and lack of awareness of these conditions does not exempt applicants from the requirement to comply with them. The Statement identifies the ethical principles and values which should govern research involving humans, and contains chapters of considerations relevant in specific research contexts.

4.2 Submit your application in a timely manner
Ethics clearance should be obtained before the commencement of activities which the HREC should review. Thus, it is not necessary to obtain clearance before you commence a literature review, but you must not commence your field work without clearance. There are some activities for which it is not entirely clear whether ethical review is required. For example, preliminary contact with people who you wish to interview is one such case. You will need to use your judgement here: consider this in terms of the HREC’s
responsibility to review activities which have a potential for infringing basic ethical principles. For example, preliminary contact in the form of requests to CEOs of organisations for permission to interview staff is unlikely to infringe any ethical principles. On the other hand, a research student making preliminary contact with street kids who she wants to interview could conceivably infringe some ethical principles, as inexperience could result in inappropriate requests or other inadvertent outcomes. If there is any doubt as to what point in your project you need ethical clearance, speak with your supervisor or contact the Executive Officer of the HREC.

There is limited provision for reviewing applications between meetings (refer to Fast-tracking of applications); therefore it is important to plan ahead and allow time for obtaining clearance prior to the proposed commencement of activities which involve humans. If your application is linked to a research grant application to a funding body such the ARC or NHMRC, it is advisable to apply well in advance of the granting body's deadline to allow sufficient time to make any amendments which may be required by the HREC.

You need to ensure that you submit your application for a meeting that falls before your planned commencement date for field work. It is also wise to consider the possibility that some additional information may be required before clearance is issued. Therefore, ethical clearance should be one of the first items to be considered when you commence planning your project.

The HREC meets approximately every six weeks. Meeting dates are published on the Web on the Research Office website at http://www.cdu.edu.au/research/office/ethicscalendar.html. Closing dates for meetings are two weeks prior to the meeting. Occasionally it is necessary to defer a meeting: if the date of clearance is critical, you should confirm the date from the Web, or by phoning the Executive Office on (08) 8946 6498.

4.3 Complete and submit the application form

All applications must be submitted on the national on-line National Ethics Application Form version two (NEAF), which is available at https://www.neaf.gov.au/ or through the link from the CDU Research Office website at: http://www.cdu.edu.au/research/office/apphec.html.

Applications must be signed by the Chief Investigator(s) and by the supervisor if the Chief Investigator is a student. The form must then be signed by the Dean of the faculty before being lodged with the HREC Executive Officer in the Research Office.

Applications should include all requested attachments. Do not include attachments additional to those requested, as it is expected that the information elicited by the questions on the form should be sufficient for the HREC to make a decision. Additional documentation, such as letters of authorisation from departments or organisations, should be kept in readiness for an audit.

Only one copy of the application is required. A copy of the form may be submitted in .pdf form by email to the HREC Executive Officer at the Research Office. However, the original, hardcopy, signed signature page(s) must be received by the Research Office by the due date for applications. Applications must be accompanied by the relevant attachments, such as Plain Language Statements, Consent Forms, Survey/Questionnaire, etc.

4.4 Submitting an application for ethical clearance for projects which have already commenced

In some circumstances, projects and activities involving humans may already have commenced prior to obtaining clearance from the HREC. This may be the result of transferring a project from another institution (eg, students transferring universities), or it may be due to failure to obtain a clearance at the appropriate time.

Irrespective of the reason, it is important to obtain a clearance as soon as possible. In the meantime all activities involving humans must be halted until clearance is obtained. Advice from your supervisor or the HREC should be sought if this is likely to impact on the successful completion of your research project.

Applications should be completed as for new projects, but you should clearly identify which activities have already been undertaken and which have not yet been commenced. Clearances are not retrospective: in other words, a clearance only applies to activities yet to be undertaken, not to activities undertaken prior to issue of the clearance. In practical terms, this does not affect you or your project, however it does mean that CDU cannot be held responsible, and is not legally liable, for activities undertaken without ethical clearance, should complaints be lodged.

4.5 Fast-tracking of applications

An explicit request to fast-track an application must be made to the Executive Officer and the conditions for consideration of fast-tracking as set out in the CDU Human Ethics Guidelines must be met. An application
accepted for fast-tracking will be forwarded to the fast-tracking subcommittee of the HREC, which generally is able to make a decision within 4 days. The decision of the subcommittee enables commencement of activities involving humans but ratification of the decision is required by the HREC, which may still require further information or modification of the project. In this case, it may place restrictions on some activity, or require the cessation of data collection, until it is satisfied that all ethical issues have been adequately dealt with.

It may also be the case that members of the fast-tracking subcommittee determine that your application requires review by the full Human Research Ethics Committee, in which case your application will be held over until the next meeting and you will be notified of this and advised to await clearance before proceeding with activities for which ethical clearance is required.

4.6 Attending a meeting of the Human Research Ethics Committee when your application is considered

In some instances, the HREC finds it beneficial to invite the Chief Investigator to attend a meeting in order to clarify some aspects of the proposal. If this is the case, the Executive Officer will contact you to arrange for you to attend the next meeting. However, if you are unable to attend a meeting, alternative arrangements for obtaining the details needed by the HREC will be made.

5. How will the Human Research Ethics Committee notify applicants of its decision?

After consideration of your application, the HREC will make its decision, of which it will notify the first named Chief Investigator in writing immediately following the meeting (allow 7 days for notification).

If all ethical issues are identified and appropriate provisions for dealing with them detailed, the HREC will approve the project and issue a clearance notice, which is signed by the Chair and forwarded to you, with a copy to your supervisor (for students) or to the Dean of your faculty (for staff).

The HREC may require further information, e.g., confirmation, clarification of aspects of the proposal; or may require amendments to the proposal. The Executive Officer will write to you as soon as practicable after the meeting to advise you of this. Depending on the importance of the information, your response may be considered immediately by the Chair, or may be referred back to the HREC at its next meeting.

The HREC may not approve the proposal and will instruct the Executive Officer to write advising you. However, this decision is extremely rare.

6. Who may be contacted for further information?

Most information required should be obtainable from the NHMRC Statement, the CDU Human Ethics Guidelines and these Guidelines. These are available from the Web or from School Offices, who can download forms and guidelines for those without access to the Web.

For information not contained in the Guidelines, contact the Executive Officer of the Human Research Ethics Committee in the Research Office by phoning (08) 8946 6498 or by fax (08) 8946 7199, or by writing to: Executive Officer, Human Research Ethics Committee, Research Office, Charles Darwin University, Darwin NT 0909.

7. Is ethical clearance from any other bodies required?

You may have to obtain ethical clearance from the ethics committee of another institution. This can occur if:

- your project is conducted at more than one institution or organisation either by the same or by different Chief Investigators;
- your project is conducted jointly by researchers affiliated with different institutions or organisations;
- you change affiliation from one institution to another during the course of your project.
- Projects falling into one of the above categories are termed "multi-centre research". Refer to Ch.3 of the Statement

Other local Human Research Ethics Committees are:

Joint Institutional Ethics Committee of the Royal Darwin Hospital and Menzies School of Health Research (JIEC). All projects conducted under the auspices of RDH and MSHR must be approved by the JIEC. This includes projects by MSHR students who are enrolled at CDU.

Northern Territory Department of Education. Research conducted within NTDE schools must be approved by the department. You will need to complete an application and attach an outline of the research proposal, a statement from your supervisor indicating approval of the proposal, a copy of any data collection instruments and a copy of letters to principals, if applicable.
8. What responsibilities does the Chief Investigator have once clearance has been given?
Once the HREC has reviewed and approved your application and issued a clearance notice you are free to commence activities which involve humans, in accordance with your proposal. However, your responsibilities in respect of ethics do not end at this point. You are responsible for ensuring the continued ethical acceptability of the project until its completion.

8.1 Changes to aspects of the project
As ethical clearance is limited strictly to the proposal as submitted to the HREC, any significant variation or modification must be notified to the HREC for further consideration and approval. Whilst it is not necessary to advise the HREC of very minor changes (eg, delay of a few weeks to commencement, change of minor personnel), all significant modifications (eg, a change in the methodology or change of Chief Investigator) should be notified, as the HREC must determine what if any new ethical implications will arise.

There is no proforma for advising of modifications. You are asked to notify the HREC in writing and provide the following details:
1. the modification proposed;
2. how you foresee will affect other aspects of the project;
3. what ethical implications you see arising from this modification;
4. how you propose to manage the project so as to minimise adverse effects and maximise the benefits to be achieved.

8.2 Renewal of clearance
Clearance is for one year only. Research projects which extend beyond one year require renewal of ethical clearance. A short renewal form must be completed, the Renewal/Final Report Form, available from http://www.cdu.edu.au/research/office/renew_final_04.rtf. This form asks you to report on the progress of your project, and seeks confirmation that you have abided by all requirements.

Note: Renewals of ethical clearances which were obtained through a Faculty Ethics Subcommittees should be submitted to the Subcommittee, using the Renewal/Final Report form.

8.3 Final Reports
A Final Report is required at the completion of your research. This should be submitted on the Progress/Final Report Form and should be submitted within three months of completion.

When the HREC considers a project to be completed depends upon whether the results of the project are expected to be published.

• If you are a student and you do not intend to publish your results, your project is deemed to be complete when you complete the unit in which you undertook the project;
• If you are a postgraduate research student, and you do not intend to publish your results, your project is deemed to be complete when you submit your thesis for examination;
• If you are a lecturer applying for clearance for a teaching project, the project is deemed to be complete when the unit ends;
• If you are a staff member or student and you intend to publish results of the research, your project is deemed to be complete when your results are submitted for publication.

8.4 Evidence of ethical clearance required for research grants
Most internal and external research grants require evidence of ethical clearance. In some cases, clearance is required before the granting body determines the award, so you will need to take this into account when preparing your timeline.

Staff awarded Research Panel grants requiring ethical clearance are required to attach a copy of their Clearance notice to their signed "Conditions of Award" and return it to the Research Office. Therefore it is advisable to plan to obtain ethics clearance as soon as possible after the decision on award of grants is made by the Research Panel.

9. Counselling Services
Research involving humans has the potential to cause distress to the participants. Researchers can sometimes alleviate that distress within the context of the research. Sometimes referral to personal counselling services is required. If there is a significant risk of the research participants experiencing distress as a result of their participation in the research, this should be addressed in the application form.
If referral to an external personal counselling service is appropriate, the service(s) need to be noted in the application, and the applicant should describe arrangements they have made to ensure the service(s) are appropriate and accessible to research participants. Information about such services and how to access them, should be included in the Plain Language Statement. Any counselling service referred to would need to have agreed in advance to offer the counselling.

If institutional counselling services are not available in the region of the research, alternative arrangements need to be clearly outlined in the application providing evidence that some form of support and counselling is available to participants.

10. Indigenous Participation and Section 4.9 of the NEAF application form

Indigenous Australians make up a large portion of the Northern Territory’s population.

Research in the NT is therefore likely to involve the participation of, or impact upon, Aboriginal and Torres Strait Islander people and/or communities.

Please address the following points:

- Describe how you have considered and addressed the following values:
- Reciprocity, Respect, Equality, Responsibility; Survival and Protection; Spirit and Integrity
- Community support for your project
- Who has ownership of traditional knowledge

Further information relevant Indigenous participation can also be found in the Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.

11. Disposal of Data

The University is committed to the disposal of records securely and in accordance with any requirements for the retention and disposal of personal information.

The disposal methods for the accumulated de-identified information and data should be conducted in the following way, as stipulated by the Australian Government Office of the Privacy Commissioner.

To protect individual’s privacy rights destruction needs to occur by secure means. Garbage disposal of intact documents leaves personal information extremely vulnerable to unauthorised access and misuse. This method of disposal should generally be avoided. Electronic records that are no longer needed should be deleted. However, it is very difficult to reliably remove all traces of electronically stored information. Organisations will need to be aware that deletion may only remove the file-reference but leave all the other information intact.

The sure disposal of paper-based records will be carried out in the following manner:

- Documents will be placed in the Charles Darwin Universities’ Confidential Bins, located in building 39, level 2 which are controlled by a contracted authorised disposal company for secure disposal, who would employ all or one of the following processes to dispose of the confidential material:
  - Shredding
  - Pulping
  - Disintegration

The sure disposal of electronic records will be carried out in the following manner:

- Records will be overwritten before they are deleted and also degaussing of the hard drive.
- As a means of good practice, all (if any) back-up files will also be disposed of in the above mentioned manner.

CDU researchers and research administrators are responsible for the proper management and retention of research data and primary materials.
This document provides guidelines on the ownership of research materials and data, their storage, their retention beyond the end of the project and appropriate access to them by the research community.

RETENTION

Sufficient data and materials should be retained from the research to justify the outcomes and to defend them if they are challenged.

In general research data must be retained for a minimum of 5 years from the date of any publication which is based upon it or the end of the project if the research has not been published. Retaining data for 15 years or more may be necessary for clinical trials. When considering the length of time that data should be retained disciplinary practice, professional standards, contractual obligations and relevant legislation, codes and guidelines must also be taken into account.

The school where the data was generated is responsible for the safe and secure storage of research data and for maintaining records of where research data are stored.

Researchers are responsible for the safe and secure storage of any original data or materials or copies that are in their possession. Arrangements for material held outside of the school repository should be documented and approved by the Head of School.

In the case of a researcher leaving CDU, the original research data shall be retained by the school and the researcher may relocate copies of the data subject to meeting appropriate storage requirements. This arrangement should be documented.

OWNERSHIP

Ownership of the research data and materials should be established prior to data collection. In general, materials and data collected by students of CDU as part of their study at CDU are the property of the student and the materials and data collected by CDU staff for research projects hosted by CDU are the property of CDU. The ownership of data may however be influenced by funding or other arrangements.

SAFETY AND SECURITY

Research data and primary materials should be retained in such a way as to avoid unauthorised access, destruction, alteration or removal, accidental or intended damage or destruction.

CONFIDENTIALITY

Confidential data is data that, in research involving humans, links the participant with the research project. It includes: identifying information such as names, addresses, signed consent forms; sensitive information such as highly personal data or data that is in a form that may indirectly identify a participant, for example a case study; and information that is not sensitive but that may identify people such as photographs.

Confidential data should be retained in a lockable filing cabinet or a lockable room with restricted access. When stored electronically, access should be controlled, for example through the use of password access.

ACCESS TO RESEARCH DATA

The verification of research must be possible. Research methods and results should be open to scrutiny and debate.

Research data should be made available to other researchers unless privacy, confidentiality or ethical issues prevent this.

DISPOSAL OF RESEARCH DATA

When the specified period of retention has finished the research data must be disposed of in a safe and secure manner. Destruction of research data must be authorised by the Head of School on the recommendation of the researcher.
Confidential research data should be destroyed in such a way to ensure the complete destruction of the information. For example:

- Paper copies may be shredded
- Electronic format may be reformatted or rewritten. Deleting is not sufficient.
- For audio-visual tapes a magnetic field bulk eraser may be used.

The method chosen should be the most effective method at the time as this may change over time.
Essential Reading
Applicants should have read and become familiar with the following documentation.

Revised NHMRC National Statement on Ethical Conduct in Research Involving Humans, 2007

NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003

The Commonwealth Privacy Act, 1998
NHMRC has issued Guidelines Under Section 95 and 95A of the Privacy Act 1988
• Section 95 http://nhmrc.gov.au/publications/synopses/e26syn.htm
• Section 95A http://nhmrc.gov.au/publications/synopses/e43syn.htm

The Northern Territory Information Act, 2002

AIATSIS Guidelines for Ethical Research in Indigenous Studies, 2000

Related Documents

CDU Human Ethics Guidelines

CDU Human Research Ethics Committee Terms of Reference

CDU HREC Clearance Process

CDU Faculty Ethics Committee Guidelines

National Ethics Application Form (NEAF)
http://www.neaf.gov.au

Form for Application for Renewal and Final Report

Sample Consent Forms

Sample Plain Language Statements / Information Sheets

CDU HREC Application Checklist

[Adapted from: Part 1 of Human Ethics Committee Guidelines for completing the application form for ethical clearance http://eagle.cdu.edu.au/ntu/apps/ntuinfo.nsf/WWWView/Procedure_739]