CDU Human Ethics Guidelines

Purpose

1. Purpose

1.1 The University's mission is to provide education, training, research and related services locally, nationally and internationally to support and advance the social, cultural, intellectual and economic development of Australia's Northern Territory.

1.2 In achieving this mission, the University recognises the importance of ethical principles in all spheres of its activity. The purpose of this document is to provide guidelines for the ethical conduct of members of the University community in relation to research and other activities involving humans conducted under the auspices of the University.

1.3 These guidelines have been developed in light of existing ethics policies at the national and institutional level. It should be read in conjunction with the policies and other documents identified herein.

Guidelines

2. Duty of Care

2.1 The University has a duty of care toward members of the university community and also toward members of the general community where the University's activities impact upon them. In respect of research and other activities requiring similar procedures which involve humans, the University fulfills its duty of care through the establishment of a system of ethical review of such activities which are conducted under its auspices. The system of ethical review conforms to national guidelines established and published by the National Health & Medical Research Council (NHMRC), the principle one being the National statement on ethical conduct in research involving humans.

2.2 The primary purpose of ethical review is for the protection of the welfare and rights of participants in research and other activities, and also non-participants who may be affected by the activities. This objective is based on the principle of respect for the inherent dignity and autonomy of individuals. Historically, the development of ethics committees to ensure protection of participants in research was in response to situations in which the welfare and rights of participants was not well protected. Where involvement of individuals has a potential for infringing basic ethical principles, review by an ethics committee is warranted.

2.3 Protection of the welfare and rights of participants entails scrutiny of the impact of research and other projects on participants' rights in relation to the following:

2.3.1 Privacy. Claims to privacy are part of the claim that the autonomy of each individual should be protected and his or her integrity respected. Individuals should not be interfered with without their consent and they should have a measure of control over their own privacy.

2.3.2 Confidentiality. Individuals have a right to expect that their wishes in regard to information given to another party in confidence will be respected.

2.3.3 Avoidance of harm. Project managers have an obligation to protect the right of individuals to be free of risk of harm, unless the risk has been explained and accepted, and can be justified in terms of the benefits likely to accrue as a result of the project. The term "harm" includes any discomfort, inconvenience, mental, physical or emotional distress, suffered by participants.

3. Ethical review system at CDU

3.1 CDU recognises that ethical review of research and other activities undertaken under its auspices is conducted at many levels and by various bodies and individuals. Researchers undertaking research themselves explicitly or implicitly conduct an ethical review of their research throughout every stage of the research project, drawing upon their own professional knowledge and referring to their professional Code of Conduct. Peer review is an established mechanism at the University, either formally through faculty committees or informally through sharing of ideas and suggestions. Lecturers using teaching tools such as surveys and personality tests, also draw upon similar resources.

3.2 It is therefore recognised that review of research proposals and some other non-research activities by an ethics committee is only one element in the overall process of ethical review. It is however, an important mechanism in assisting the University to meet its duty of care through the identification of
ethical issues which need to be addressed by researchers, lecturers and students, and through its educative role vis à vis applicants.

3.3 The Human Research Ethics Committee is constituted and operates in accordance with the NHMRC National Statement on ethical conduct in research involving humans.

3.4 The Committee was established by the Vice-Chancellor and reports to the Vice-Chancellor's delegate, the Deputy Vice-Chancellor (Research and International). Administration is the responsibility of the Research Office.

3.5 To assist the HREC with its workload, Faculty Ethics Committees have been established in some faculties. These have their own guidelines and application proforma, and are designed to review minor projects and make recommendations regarding ethical clearance to the HREC, which has final authority in respect of giving ethical clearance. The HREC Guidelines contain instructions about which committee applications for ethical clearance should be submitted.

4. Activities requiring ethical review

4.1 Certain specific activities which involve humans, either as participants in the research or other activity, or as members of a group upon whom the activity impacts, require ethical review. The types of activities are outlined below. The Human Research Ethics Committee guidelines assist further with the identification of projects which must be submitted to Human Research Ethics Committee for review.

4.2 Research projects

In line with the national guidelines on ethics in research involving humans, all University staff and students who intend to undertake research involving humans are required to obtain ethics clearance from the Human Research Ethics Committee. Where ethical clearance is required for projects funded or administered by the Research Panel, funds will not be released until ethical clearance has been obtained.

4.3 Non-research activities

A number of other activities conducted routinely within a university environment have the potential for infringing upon the rights and welfare of individuals and therefore also merit ethical review. 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).

5. Compliance

5.1 Ethical clearance for research must be obtained prior to the commencement of activities involving humans. Where applications are submitted to a Faculty Ethics Committee, that committee may issue a provisional clearance, which enables commencement of activities involving humans, pending a final clearance by the HREC.

5.2 The HREC guidelines provide specific instructions on the timing of applications.

5.3 University staff and students are expected to make themselves aware of, and comply with, all University policies. Non-compliance with any University policy is regarded seriously by the University and wilful disregard of a policy constitutes misconduct. Staff and students who fail to comply with the requirements of this policy are liable to the imposition of penalties.

6. Review by the Human Research Ethics Committee

6.1 The Human Research Ethics Committee reviews proposals in accordance with its terms of reference and in line with NHMRC guidelines, the Committee's guidelines and other relevant University policies and processes. Decisions on ethical clearance are made at a quorate meeting and are normally based on a consensus vote but may be by simple majority.

6.2 All applications are treated confidentially and any information provided is be used only for the purposes of ethical review by the Committee. In its deliberations, the Committee may seek advice from qualified persons who will be bound to respect the same level of confidentiality as the Committee members. The name of the researcher or other identifying details will not be divulged.

6.3 Fast-tracking of applications

There is limited provision for the fast-tracking of applications. Fast-tracking of applications may be approved if the following conditions are satisfied:

- There is an imperative that the project must commence before the next meeting of the Human Research Ethics Committee
- The proposed research does not involve any novel or untested procedures;
• Members of the Human Research Ethics Committee are familiar with the procedures proposed;
• The application form is complete and no further information is required.

The Human Research Ethics Committee Guidelines detail procedures for timing of applications and requests for fast-tracking.

6.4 Multi-centre projects

Multi-centre, or cross-institutional, projects are research projects which involve more than one university or organisation. Each university or organisation will have its own requirements regarding ethical clearance. The CDU requires ethical clearance from the HREC irrespective of whether clearance has already been obtained from an ethics committee of another organisation. However, proposals for which clearance has already been obtained from another ethics committee may be fast-tracked, if the conditions for fast-tracking are met and the application form submitted to the organisation from which clearance was obtained and the clearance notice are attached to the application form. The Human Research Ethics Committee guidelines provide instructions on obtaining clearance for multi-centre projects.

Staff and students of CDU are required to comply with the ethics policies and guidelines of other organisations, as applicable.

7. Storage of data

7.1 Certain requirements in relation to retention of data collected for research projects apply. There are no requirements in relation to data collected for non-research activities.

7.2 The Joint NHMRC/AVCC Statement and guidelines on research practice provides the following recommendation on storage of data:

*Data must be held for sufficient time to allow reference. For data that is published this may be for as long as interest and discussion persists following publication. It is recommended that the minimum period for retention is at least 5 years from the date of publication but for specific types of research, such as clinical research, 15 years may be more appropriate. Please detail the proposed storage and access arrangements for data both during and at the completion of the project. You need to confirm that original data (where possible) will be held within the research unit in which you are based, or elsewhere in the University or another institution for a minimum of five years.*

7.3 Research data collected under the auspices of the University must be stored for a minimum of five years, with the exception of projects in which the chief investigator is a student who does not intend to publish results. The Chief Investigator is responsible for the storage and retention of original data pertaining to the project until the completion of the project.

7.4 Individual researchers may hold copies of the data for their own use, however original data must be held in secure storage at the University or other institution, not in a private residence. Wherever possible data should be retained in the Faculty or research unit in which they are generated. Most faculties have procedures in place in accordance with the CDU Code of Conduct for Research. The University Library can advise on the central storage facility of the University.

7.5 There are many complications in the issue of data storage, especially in relation to electronic data, eg, changing of data by third parties, security, etc. These issues require careful consideration by the investigators.

8. Appeals against decisions of the Human Research Ethics Committee

8.1 A person who has submitted an application to the Human Research Ethics Committee and who is not satisfied with the decision of the Committee shall be encouraged in the first instance to engage in dialogue with the committee and to seek resolution through the Committee. If additional information becomes available which is relevant to the decision but which was not provided at the time, it should be submitted to the Committee along with a request for reconsideration of the decision.

8.2 The following procedure applies where applicants wish to lodge an appeal.

8.2.1 Rights of Appeal to Appeals Panel

(i) Where a decision is made by the Human Research Ethics Committee, the appellant may appeal within 6 months of the date of notice of the decision. Appeals must set out the grounds of the appeal and must be in writing, setting out the nature of the decision of the Committee and providing evidence of the grounds for appeal.

(ii) Appeals will be considered only against process issues and not against decisions by the Committee in relation to substantive issues.
(iii) Additional information which is relevant to the decision but which was not provided by due dates as required shall not be admitted as evidence.

8.2.2 Establishment of an Appeals Panel

(i) On receiving a notice of appeal, the Committee shall notify the Vice-Chancellor.

(ii) The Vice-Chancellor shall establish an appeals panel in accordance with the following provisions:

(iii) An appeals panel shall consist of:

- a Chair, who shall be a Deputy Vice-Chancellor but excluding any persons who were involved in the original decision;
- one or more University staff members, including at least one senior staff member, none of whom were involved in the original decision.

(iv) The appeals panel shall include both genders.

(v) The Vice-Chancellor shall not appoint to the appeals panel any person who, in the Vice-Chancellor's opinion, should be debarred from participating in the appeal by reason of his or her involvement in any matter.

(vi) A member of the Research Office shall act as secretary to the appeals panel.

8.2.3 Hearings and Powers of Appeals Panel

(i) The powers of the appeals panel are to:

- confirm the decision of the Human Research Ethics Committee; or
- identify deficiencies in the procedure of the Committee; and
- require the Human Research Ethics Committee to address such deficiencies identified in the appeal process.

(ii) An appeals panel shall begin hearing an appeal as soon as practicable after the appellant gives notice of the grounds of his or her appeal.

(iii) Where any member of the panel becomes unable to attend, the Vice-Chancellor shall establish a new panel, which shall commence its hearing as soon as may be.

(iv) The secretary to the appeals panel shall give to each of the parties to the appeal not less than seven days clear notice of the date, time and place of the hearing.

(v) The panel shall be entitled to call witnesses, and to cross examine witnesses called by the appellant.

(vi) The decision of an appeals panel shall be by majority vote, the Chair having primary vote only.

(vii) Any point of law arising on an appeal shall be decided by the Chair of the appeals panel.

(viii) Where a appellant fails to appear at a hearing at which notice has been duly given, an appeals panel may at its discretion either proceed with the hearing in the appellant's absence, or adjourn it.

(ix) The secretary shall give written notice of the decision of the appeals panel to the appellant within 7 days of the decision.

(x) Once the appeals panel has made its decision in relation to the appeal, no further consideration of the issue will be undertaken by the University.

8.2.4 Rights of the appellant during an appeal hearing

(i) The appellant shall be entitled to be accompanied by a person, who may speak on behalf of the appellant if the appellant expressly requests this.

(ii) The appellant shall be entitled to be present throughout the appeals hearing, except when the Chair and members wish to confer privately among themselves or to consider their decision.

(iii) The appellant shall be entitled to address the panel, to call and examine witnesses, and to cross-examine other witnesses.

(iv) The appellant shall be entitled to submit written submissions to the panel, either prior to the hearing or at the hearing.

(v) The appellant shall be entitled to request accommodation of any special needs which he or she may have in relation to his or her disability, or a disability of the person accompanying the appellant. All reasonable requests will be accommodated to the best of the University's ability.
8.2.3 Giving of Notices

(i) A notice is given to a person if it is either given to him or her in person, or mailed by registered post to the last address known to the University as his or her postal address.

(ii) The date on which a notice is given is a reference to the date of the letter in which advice of the appeals panel meeting date is given.

9. Ethical misconduct and complaints

9.1 The Human Research Ethics Committee has developed a mechanism for responding to complaints about research or other activities which are covered by the Human Research Ethics Guidelines.

9.2 Any individual or organisation may initiate a complaint about research involving humans by making a written complaint to the Executive Officer of the Human Research Ethics Committee, who will act as the Complaints Officer. Complaints may refer to:

• activities being conducted in a way which the complainant believes to be unethical or contrary to existing policy or legislation;
• activities being conducted without formal approval by the Human Research Ethics Committee;
• activities being conducted in a manner contrary to an ethics application which has been approved by the Committee;
• activities being conducted in manner contrary to the conditions placed on the activity in the letter of approval from the Committee;
• violation or compromise of confidentiality in recruitment, conduct and publication of research;
• misuse of data;
• any other similar matter.

9.3 All complaints received will be investigated where the complainant identifies him or herself. Anonymous complaints received by the Complaints Officer will be filed, but will not be investigated.

9.4 On receiving a complaint, the Complaints Officer, in consultation with the Chair of the Human Research Ethics Committee, will take one of the following actions in light of the information contained in the complaint:

• Inform the chief investigator (and supervisor where applicable) of the complaint and seek a response to the complaint;
• Seek an explanation of the events which have given rise to the complaint;
• Suspend Human Research Ethics Committee approval while the matter is investigated;
• Request evidence that the chief investigator is conducting the project in keeping with the terms of the Human Research Ethics Committee approval;
• Place further conditions on the continued conduct of the project;
• Require that all or some data be brought to the Complaints Officer for secure storage;
• Approach the Deputy Vice-Chancellor (Research and International) to inform him/her of the complaint;
• Recommend further investigation of the complaint by the Deputy Vice-Chancellor (Research and International);
• After full investigation, revoke approval for the research and require that all data that has been collected be brought to the Complaints Officer for secure storage.

9.5 Complainants and investigators (and supervisors where the research is student research) will receive a written response to the complaint from the Complaints Officer on behalf of the Human Research Ethics Committee. Where the nature of the complaint requires further investigation, researchers will receive written information on the progress of the investigation being undertaken.

9.6 Researchers who believe that a complaint is unwarranted or that the handling of the complaint is unfair are entitled to lodge a formal complaint or appeal to the Vice Chancellor.

10. Review of human ethics procedures and guidelines

10.1 The ethical procedures and guidelines of the Charles Darwin University and its Human Research Ethics Committee are reviewed regularly by the Committee to ensure that they are congruent with societal values, legal requirements, NHMRC guidelines, research practice and University policy.
Essential Reading
Applicants should have read and become familiar with the following documentation.

NHMRC National Statement on Ethical Conduct in Research Involving Humans, 1999

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

The Northern Territory Information Act, 2002

AIATSIS Guidelines for Ethical Research in Indigenous Studies, 2000

Related Documents
CDU HREC 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 ‘CDU Human Ethics Policy’: http://www.cdu.edu.au/research/office/CDUHumanEthicsPolicy.htm ]