

A. ETHICAL STANDARDS POLICY

A policy for ensuring the protection of the rights and dignity of human subjects involved in University research.

PREAMBLE

Research involving humans as subjects is important for the advancement of knowledge in the sphere of human welfare. It is recognised that University research has made a substantial contribution to the welfare of society and that its effective continuation is vital to society and to the academic activities of the University. It is clear that most research with humans has been conducted with a strong sense of professional ethics and responsibility. It is acknowledged that researchers have a sense of gratitude to those who have participated in their studies and that continuing good-will between researchers and subjects is vital for creative research.

That the rights and dignity of all subjects be protected by a policy statement of Ethical Standards and Procedures is seen as an important aspect of protecting this relationship. Research, and associated class-projects, must be conducted with extreme care with regard to the rights and welfare of the individuals who volunteer as subjects.

The climate in which human research may be conducted is highly sensitive in terms of public reaction, availability of funding, and legal liability. It is envisaged that external agencies funding research will increasingly require an institutional review of the ethical standards of proposed research as a condition for their consideration of applications for funds. In this regard, it is recognised that staff members conducting and supervising research and class projects have the primary responsibility because it is they who have detailed knowledge of the project and of working directly with subjects. It is affirmed also that the institution, under whose auspices human research is conducted, has direct responsibility to the subjects of that research.

The rights and welfare of all who contribute to the advancement of knowledge by their participation as subjects in University research activities are of prime importance to the University. Consequently, these rights must be protected by conscientious scrutiny of each University research project and class project in order to identify all foreseeable risks. In addition, all subjects should be afforded the opportunity to protect themselves, and should participate only by express consent, freely given after having received adequate information about the project in order to evaluate the risks that may be encountered as well as the legal limitations to anonymity and confidentiality. Finally, subjects must be able to rely on the researcher to respect their privacy, to maintain anonymous status, and to keep confidential all data collected pursuant to participation in the project within the legal limitations referred to above.

The policy described herein is designed to support and reinforce ethical standards, and to provide the formal mechanisms for endorsement by the University of academic and research programmes utilizing human subjects.

SCOPE

The Policy on Ethics with respect to the use of Human Subjects at Rhodes University shall apply to the use of human subjects in all University research and class projects.¹ In addition, the policy shall apply to research involving the use of University facilities by outside persons/agencies operating under an agreement with the University.

DEFINITIONS AND INTERPRETATION

I. Class Project

A classroom demonstration/practical laboratory exercise or a research project assigned by the instructor as part of the learning-teaching plan of a course is defined as a class project. Thesis research does not fall within this category, but within the category of University research projects. In this connection ensuring that the Ethical Guidelines of the University are complied with is normally a responsibility of the Department concerned, although a Department may request review of a particular proposed class project by the Ethical Standards Committee.

II. University Research Project

All research projects carried out by postgraduate students and/or Staff of Rhodes University, or by outside agencies but using Rhodes' facilities fall within this category.

III. Project Supervisor and Research Assistant

The project supervisor is a staff member who is carrying out an independent research project, or who is supervising a graduate or undergraduate student engaged in a research project, or who is the lecturer supervising a class project/practical.

Students or other persons authorised by the project supervisor to carry out the project are research assistants.

IV. Protocol

The description of the project to be submitted to the Department of Human Subjects Committee or the University Ethical Standards Committee is called the protocol.

(See APPENDIX 1 for a copy of the protocol relative to Human Subjects Research)

POLICY

1. GENERAL POLICY

- 1.1 The Policy, Procedures and Ethical Guidelines adopted by the University are binding upon all University researchers and lecturers. Primary responsibility for ensuring that these policies and procedures are adhered to rests with the Project Supervisor.
- 1.2 The University research projects of concern here are those deemed to involve the use of human subjects and must be approved before commencement of the project where they involve:
- (a) personal or physical observation of, or contact with, a human subject or community.
 - (b) the eliciting of personal information from or about a human subject, including use of personal records of an institution;
 - (c) experimental therapeutic or non-therapeutic research on a human subject;
 - (d) interviewing and interview procedures; or
 - (e) the use in a new research project of stored confidential data originally collected by any of the preceding methods.
 - (f) the use of tissues of human origin.
- 1.3 Where class projects involve the use of human subjects as described in 1.2, the projects must conform to the relevant Ethical Guidelines adopted by the University. It is recognised, however, that certain learning-teaching activities involving human subjects are so proliferated and of such an innocuous nature that the lecturer has no option but to exercise his professional discretion in determining whether a formal approval by the University would be required. Where such lecturers have any doubt about the capability of the project to meet the standard Guidelines, they should consult their Department Human Subjects Committee or the University Ethical Standards Committee to determine if the project should obtain formal approval.
- It is incumbent upon lecturers to make student investigators aware of the Policy, Procedures and Ethical Guidelines for use of human subjects in academic affairs, and to ascertain that the students involved are competent to maintain the standards.
- 1.4 Nothing in this policy document should be interpreted as relieving a University researcher, lecturer or research assistant of any obligations acquired as a result of

membership of a professional association. However, adherence to a professional code of ethics does not in itself override the obligation to observe the procedures set out here, where they normally would apply.

- 1.5 The committees established to implement this policy have discretion in applying the Ethical Guidelines where exceptional circumstances or common sense dictate, provided that the basic principles underlying the policy are not compromised.

2. DEPARTMENT HUMAN SUBJECTS COMMITTEE (SEE B2 FOR PROCEDURES)

2.1 Where there is a substantial number of university research projects or class projects which use, as human subjects, students enrolled in courses given by a Department or children enrolled in Departmental programmes, or which involve human subjects in thesis research done by students in the Department, that Department should establish a Department Human Subjects Committee.

2.2 Membership

- (a) the Department Human Subjects Committee to be established by the H.O.D. shall consist of:
- i) The H.O.D. or his/her designate;
 - ii) at least two departmental staff members active in investigations involving human subjects;
 - iii) such **ad hoc** members as may be named by the committee to deal with particular protocols, including student members where appropriate.
- (b) Membership of the Committee will be for a one year term, but members may be re-appointed annually.

2.3 Functions and Responsibilities

- (a) In the following three circumstances, the Committee will review protocols submitted for University research projects and class projects in order to ensure that, in their use of human subjects, such projects will meet the ethical standards adopted by the University:
- i) where the project uses students enrolled in courses given by the Department or children enrolled in Departmental programmes (but see 3.3 (a) iv);

- ii) where the project involves human subjects in thesis research conducted by students *or* staff in the Department.
- iii) where the project involves human subjects in non thesis research by students or Staff in the Department (but see 3.3 (a) i).

Protocols for all other projects shall be reviewed by the University Ethical Standards Committee (see 3.3a).

- (b) The Department Human Subjects Committee may confer approval on the protocol. Alternatively, the Committee may suggest amendments, in consultation with the project supervisor, particularly where a discrepancy is perceived between the protocol and the Ethical Guidelines. The Committee may require a project to be monitored in such a manner as deemed appropriate.
- (c) The Department Human Subjects Committee will refer the matter to the University's Ethical Standards Committee where:
 - i) the project supervisor is unable to agree to the alterations suggested by the Department Human Subjects Committee, and where the project supervisor wishes the decision of that Committee to be reviewed;
 - ii) a minority of the Committee wishes to register dissent from the approval of a protocol given by that Committee.
- (d) The Department Human Subjects Committee will retain on file, for the Ethical Standards Committee, a copy of each protocol reviewed by it, with amendments if any, and a record of the decision taken by the Committee immediately after the review is completed. If *ad hoc* members were consulted in the course of making the decision, that fact should be noted.
- (e) The Committee will investigate, and attempt to satisfy, objections concerning ethical standards in any on-going or completed project which is subject to review by the Committee. Where a dispute cannot be resolved, the Committee will refer the matter to the University Ethical Standards Committee.

3. UNIVERSITY ETHICAL STANDARDS COMMITTEE

3.1 The University Ethical Standards Committee shall constitute a standing committee of the Senate.

3.2 Membership

- (a) The University Ethical Standards Committee should comprise the Dean of each Faculty or their nominees, as well as the Dean of Research and his/her nominee, and a representative of the medical profession. Where possible, continuity on the Committee will be ensured by staggering the appointments. The above should take effect from 1998.
- (b) The Chairman shall be elected by the members of the Committee for a two-year term.
- (c) The Chairman of the University Ethical Standards Committee shall be free to invite ad hoc members to deal with particular protocols.
- (d) Membership of the Committee will be for an initial two-year term, but members may be re-appointed.

3.3 Functions and Responsibilities

- (a) The University Ethical Standards Committee shall review protocols submitted for University research projects and class projects in order to ensure that such projects will, in their use of human subjects, meet the ethical standards adopted by the University where the project:
 - i) involves an application for funding to an external research sponsor or to grant programmes administered by the University, and where human subjects will participate;
 - ii) is a University research project or a class project which is funded internally, or which does not require funding, excluding those projects assessed by the Department Human Subjects Committee under Part 2 of this policy;
 - iii) originates in a Department which does not have a Department Human Subjects Committee;
 - iv) involves an application to an institution or organization to use its members, who are legal minors, as human subjects.
- (b) The University Ethical Standards Committee may confer approval on the protocol of such a project. Alternately, the Committee may suggest amendments to the protocol, in consultation with the project supervisor, where a discrepancy is perceived between the protocol and the standard Guidelines. The Committee may require a project to be monitored in such manner as it deems appropriate.

- (c) The approval of the Committee under 3.3a constitutes approval of the ethical standard by the University where required by a funding agency or sponsor.
- (d) The University Ethical Standards Committee will refer the matter to the Senate where:
 - i) the project supervisor is not prepared to alter the research protocol in order to conform to the suggestions of the Committee, and the project supervisor wishes the decision of the Committee to be reviewed;
 - ii) a minority of the Committee wishes to register dissent from the approval, given by the Committee, of a protocol.
- (e) The Committee will investigate, and attempt to satisfy, objections concerning ethical standards in any ongoing or completed project which was subject to review by that Committee. Where a dispute cannot be resolved the Committee will refer the matter to the Senate.
- (f) The Committee will clarify and interpret the Policy, Procedures and Ethical Guidelines where necessary, and may from time to time recommend procedural and policy changes to the Senate as well as providing information to staff as appropriate.
- (g) The Committee will conduct a review of the performance of each Department Human Subjects Committee at least once in every four years.