

## B. ETHICAL STANDARDS PROCEDURES

Procedures for ensuring the effective implementation of the Ethical Standards Policy.

### PROCEDURES

#### 1. REQUEST FOR REVIEW

- 1.1 The project supervisor shall initiate a request for approval of a University research project or class project involving human subjects or the handling and use of animals in research as follows:
- (a) Where a university research project or class activity is subject to review by a Department Human Subjects Committee (i) because it proposes to use students enrolled in departmental activities, as human subjects, or because the project consists of thesis research of a student in the department and proposes to use human subjects from any source, or (ii) because the project involves the handling and use of animals in research, the project supervisor will submit the protocol to the appropriate Departmental Human Subjects Committee at least two weeks in advance of the proposed date of commencement of the project.
  - (b) Where the project involves an application to an external research sponsor or for grants administered by the University, the project supervisor will submit the protocol to the University Ethical Standards Committee at least three weeks in advance of the deadline date for applications to the sponsor. The Registrar's Office will process only such applications as have been accorded University Ethical Standards Committee approval.
  - (c) Where a University research project or a class project will not be reviewed by a Department Ethical Standards Committee, the project supervisor will submit the protocol to the University Ethical Standards Committee at least two weeks in advance of the proposed date of commencement of the project.
  - (d) Where a University research project or a class project involves application to a school board to use pupils as subjects the project supervisor will submit the protocol to the University Ethical Standards Committee at least two weeks in advance of the deadline date for receipt of application by the school board.

**2. REVIEW BY THE DEPARTMENT HUMAN SUBJECTS COMMITTEE OR THE UNIVERSITY ETHICAL STANDARDS COMMITTEE.**

- 2.1 The project supervisor will be afforded an opportunity by the Department Human Subjects Committee to support and clarify his protocol, but the deliberations of the Committee shall be held in camera.
- 2.2 Where, in the opinion of the Department Human Subjects Committee, a protocol should be appraised by a medical doctor, the Chairman of the Committee will obtain the opinion of a medical doctor.
- 2.3 The Department Human Subjects Committee may either approve the protocol or return the protocol with the Committee's suggestions for amendment.
- 2.4 Where the project supervisor cannot agree to alter his protocol so as to conform to the suggestions of the Department Human Subjects Committee, and the project supervisor wishes to appeal against the decision of the Committee, he shall so notify the Chairman of that Department Human Subjects Committee, who in turn will transmit brief written reasons for the decision of his Committee to the University Ethical Standards Committee.
- 2.5 Where a minority of the Department Human Subject Committee wishes to register a dissent from an approval given by that Committee, the minority shall prepare written reasons and notify the Chairman of the Committee of its dissent. The Chairman of the Department Human Subjects Committee will transmit to the University Ethical Standards Committee the written dissent together with brief written reasons for the decision of his Committee. The University Ethical Standards Committee must be notified of the dissent within seven days of the Committee decision dissented from.
- 2.6 Where a project supervisor contemplates altering substantially any element of a University research project or a class project from which a protocol was approved, either before or after commencement of the project, the researcher shall consult with the Chairman of the Committee which reviewed the protocol about the alteration. It is within the discretion of the Chairman to refer the matter for the opinion of the Committee, or to approve it on his own authority.
- The project supervisor must exercise professional discretion in determining whether a contemplated alteration is substantial; however, any change which imports deception or risk, or reduced protection of the subject's anonymity, or the confidentiality of data collected, is deemed to be substantial for the purposes of this policy and in such a case the proposed change will be referred to the Committee which reviewed the protocol.
- 2.7 The Department Human Subjects Committee may require a University research project or a class project to be monitored in such a manner as it deems

appropriate. The Committee will particularly consider prescribing monitoring in the case of student projects under the supervision of a staff member.

- 2.8 Where any objection to an ongoing or complete University research project or a class project is raised, it is the responsibility of the Chairman of the appropriate Department Human Subjects Committee to investigate the matter, and to attempt to resolve the problem in consultation with the project supervisor. Where the objection cannot be resolved, the Committee will refer the matter to the Head of the Department of the project supervisor, in the case of a class project, or to the University Ethical Standards Committee, in the case of any other research project.

Notice of such objections will be given to the Head of the Department of the project supervisor regardless of the resolution.

- 2.9 Decisions of the Department Human Subjects Committee shall be majority decisions.
- 2.10 Except as they are expressly set out here, the Department Human Subjects Committees and the University Ethical Standards Committee shall develop their own procedures.

### **3. REPORTING BY DEPARTMENT HUMAN SUBJECTS COMMITTEES**

- 3.1 The Head of the Department shall notify the University Ethical Standards Committee of the formation of a Department Human Subjects Committee, and of the names of the members of the Committee from year to year.
- 3.2 The Department Human Subjects Committees shall maintain a file, on behalf of the University Ethical Standards Committee, of each protocol reviewed by them, with amendments, if any, and a record of the decision taken by the Committee. If **ad hoc** members were consulted in the course of making the decision, the fact will be noted. The Committees shall also keep on file any formal minutes of their meetings. These records should be available at any time for scrutiny by the University Ethical Standards Committee.

### **4. APPEALS**

- 4.1 Where a decision of a Department Human Subjects Committee or of the University Ethical Standards Committee is the subject of appeal by the project supervisor or by a dissenting member of the Department Human Subjects Committee, the University Ethical Standards Committee shall record the written reasons for the decision of the Department Human Subjects Committee under appeal, and the written dissent, if any.

- 4.2 Where any objection to an ongoing or completed University research project is not resolved, the matter may be taken on appeal to the University Ethical Standards Committee.
- 4.3 On appeal, the University Ethical Standards Committee shall invite the project supervisor to support his project, but the deliberations of the University Ethical Standards Committee will be held in camera.
- 4.4 When a matter is taken on appeal the University Ethical Standards Committee may confirm or modify the decision previously taken with regard to the project. The Committee may impose its own conditions for approval of the project, or for its continuation. The Committee may further halt an ongoing project pending recourse through other channels.

## **5. REPORTING ON COMPLETED PROJECTS**

A brief report must be submitted on the completion of every research programme that has been granted ethical approval. The report should be submitted to the relevant committee and should include the following information. Title of project; researchers; ethical approval number; very brief summary of results and conclusions; importantly, whether there were any unforeseen and undesirable consequences and if so, the steps that were taken to rectify them; whether the results have been published and if so a full reference.

A copy of the report will be kept with the original application for ethical approval and the committee reserves the right to access the research findings.