Human Subject Research Ethics Policy

**Purpose**

1. The purpose of this policy is:
   a) to create a research environment in which human subjects, human remains and human biological materials are respected and protected,
   b) to ensure compliance with relevant legislation and regulation,
   c) to ensure responsibilities are discharged in accordance with the University’s expectations; and
   d) to promote an awareness of ethics within the University community.

**Scope**

2. This policy applies to Research involving human subjects:
   a) that is conducted by University of Calgary Faculty, Staff, or Students;
   b) that is undertaken under the auspices of or in Affiliation with the University of Calgary; or
   c) that uses University of Calgary equipment, facilities space or resources.

**Definitions**

3. In this policy
   a) “Affiliation” describes a close connection or formal relationship. An Affiliate is an organization that has a close connection to or formal relationship with the University of Calgary.
b) “Faculty” means an individual who holds an academic staff appointment.

c) “Research” means a detailed study of a subject in order to discover information, acquire knowledge, or gain understanding. In this policy, the term “study” is interchangeable with “research”.

d) “Research Ethics Board” includes the Conjoint Faculties Research Ethics Board (CFREB) and the Conjoint Health Research Ethics Board (CHREB).

e) “Staff” means an individual employed by the University of Calgary and an individual employed by a Faculty member.

f) “Student” means an individual registered in a course and/or program of study at the University of Calgary as well as an individual visiting the University of Calgary and using University of Calgary facilities, equipment or resources to conduct their program of study.

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Objective

4.1 Research involving human subjects will be conducted in accordance with the University’s ethical standards in every aspect of the process including applications, proposals, the research itself, reports and publications.

Regulatory Framework

4.2 Research involving human subjects will be carried out in accordance with the most recent version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) as well as other provincial, national and international standards when required or appropriate.

Research Ethics Boards

4.3 Research involving human subjects will be reviewed by a Research Ethics Board or Committee. In some cases, a Research project may need to be reviewed by more than one Board or Committee.

4.4 Research involving human subjects will not be undertaken if it has not received formal ethical approval by the appropriate Research Ethics Board. In addition:
   a) services, facilities, and space at the University or at Affiliated organizations will not be used for such purposes,
   b) funds allocated for such purposes will not be accepted, and
   c) accounts to deposit funds for such purposes will not be opened.

4.5 A researcher may request reconsideration of an interim decision made by the Research Ethics Board.

4.6 Decisions made by the Research Ethics Board may be appealed to the
Research Ethics Appeal Board (REAB) on grounds of breach of procedural justice.

4.7 The REAB will maintain procedures governing the conduct of appeal hearings.

Accountability

4.8 The responsible head or director of the academic unit will ensure that those who conduct Research and those who are being trained to conduct Research:
   a) understand their responsibilities,
   b) receive appropriate training in the skills necessary for the ethical conduct of such Research, and
   c) are aware of the standards relevant to the particular area of Research.

4.9 Individuals who undertake activities that fall within the scope of this policy will be thoroughly familiar with and will comply with applicable requirements.

Violations

4.10 Violators of this policy may lose the privilege of carrying out Research involving human subjects and may also be subject to penalties under University regulations, collective agreements, and under provincial and federal law.

Responsibilities

5 5.1 Approval Authority
   a) ensures appropriate rigour and due diligence in the development or revision of this policy

5.2 CFREB
   a) primarily responsible for examining any human subject research proposal or project submitted or otherwise referred to it to ensure that it meets acceptable ethical standards. It has the authority to approve a protocol, approve a protocol with modifications, or reject a protocol.

5.3 CHREB
   a) responsible for the review of human subject research protocols covered by an Affiliation Agreement entered into between the University, primarily on behalf of the Faculties of Medicine, Kinesiology and Nursing and another institution, organization or body. It is responsible for examining any research proposal or project submitted or otherwise referred to it to ensure that it meets acceptable ethical standards. It has the authority to approve a protocol, approve a protocol with modifications, or reject a protocol.

5.4 Faculty/Departmental Ethics Committees
   a) responsible for reviewing any undergraduate course-based research
projects that involve research on human subjects, and/or are a component of the pedagogical process (applies to those faculties/departments that have Faculty/Department Ethics Committees).

5.5 Implementation Authority
a) ensures that University staff are aware of and understand the implications of this policy and related procedures; monitors compliance with the policy and related procedures; regularly reviews the policy and related procedures to ensure consistency in practice; sponsors the revision of this policy and related procedures when necessary; and appoints a Policy Advisor to administer and manage these activities.

5.6 The Research Ethics Appeal Board (REAB)
a) hears and decides appeals of CFREB or CHREB decisions.

Appendices
- 6  CFREB Terms of Reference
-  CHREB Terms of Reference
-  REAB Terms of Reference
-  Research Ethics Website
-  Affiliations
-  Calgary Health Research Ethics Process

Procedures
- 7  Under development

Related Policies
- 8  Animal Care and Use Policy

References
- 9  ARECCI
-  Title

History
- 10  Drafted: Spring 2008

Approved: June 26, 2008 by General Faculties Council

Effective: June 26, 2008