Ethics Review of Research Involving Human Subjects[1]

IUBAT is committed to ensuring the highest level of ethical conduct for research involving human subjects. Review of research proposals by a Research Ethics Committee provides accountability and quality assurance both to colleagues and to society.

Policy

This Policy provides a mechanism for ethics review of research involving human subjects to protect those subjects, researchers, support staff, students, and third parties, and to educate those involved in this type of research. Its procedures are consistent with the educational and research mandates of IUBAT and respect the academic freedom and responsibilities of faculty members and the principle of informed consent with respect to potential subjects.

1. Requirement for Ethics Review

1.1 In general, all research involving human participants requires ethics approval. This includes research conducted by any employee or student of IUBAT, or Adjunct Faculty or visiting students, interns or scholars. Where external agencies or non-IUBAT researchers are involved they should also follow the policies of their parent organization. In the case of doubt, applicants should seek advice from the Vice-Chancellor's Office regarding the potential need and the process for ethics review.

1.2 Research involving living human subjects occurs when data are derived from:

a. information that is collected through intervention or interaction with a living individual (e.g., interviews, questionnaires, observations taken that are noticeable by the individual);
b. secondary sources/non-public sources (e.g., interviews about a living individual, company personnel records, student records collected by an educational institution);
c. identifiable private information about a living individual.

1.3 Research in the public domain about a living individual, based exclusively on publicly available information, documents, records, works, performances, actuarial materials, or third party interviews, is not required to undergo research ethics review. However, such research requires ethics review if the individual is approached directly for interviews or for access to private papers.

1.4 All course-based research assignments involving living human subjects, require ethics review and approval (see section 6.3).

1.5 Certain classes of research involving human subjects are excluded from the requirement of ethics review by IUBAT:

[1] This policy statement is largely adapted from similar policies developed by Simon Fraser University, Burnaby Canada.

a. research conducted by a member of the academic staff as an outside professional activity, or by other employees or students, as long as the research data are not collected by asserting connection or affiliation with IUBAT, and the results are not disseminated in the public domain indicating association with IUBAT, and the research is not conducted at IUBAT or using IUBAT resources;
b. research undertaken by students outside the auspices of IUBAT and/or its academic programs (e.g., students on co-op or work terms outside the University) that does not require IUBAT resources and is not directly supervised by IUBAT faculty;
c. research undertaken by Adjunct Faculty outside the auspices of IUBAT and/or its academic programs that does not require IUBAT resources.

1.6 Research on public policy issues, public institutions, and other matters that in a free and democratic society can properly be considered as part of the public domain is not required to undergo ethics review, even when interviews with individuals occupying positions connected to such matters are involved. Public policy is defined as follows:

a. Research protocols that require contact with human participants as part of the study and whose regular occupational duties involve communicating with the public on behalf of their organizations (such as public relations officers, official spokespersons, diplomatic officials, freedom of information officers, archivists, etc., or the Chief Executive of an organization) do not require ethics review, to the degree that answering questions posed by the public is within the ordinary duties of the participant and are within the acceptable limits of disclosure defined by the participants' employers;
b. Research protocols in which inquiries are referred to other members of an organization by a public-relations officer, official spokesperson, etc., of the organization, do not require ethics review, to the degree that their inquiries are in keeping with the initial protocol and the substance of the interviews are attributable.

1.7 The opinion of the Vice-Chancellor's Office should be sought whenever there is doubt whether or not a particular research project requires ethics review.

2. Researchers' Procedural Responsibilities

2.1 In supervised research, the term "researcher" is defined as including both the supervisor and the individual(s) being supervised. When a graduate or undergraduate student is shown as the principal investigator on an application, the supervisor of the student is always the co-investigator.

2.2 It is the responsibility of researchers to obtain ethical approval as described in this policy for any project, funded or not, involving human subjects before commencing the research.

2.3 It is the responsibility of researchers to ensure that there is adequate lead time available for ethical review in relation to other deadlines.

2.4 Project funds will not be released by the University to the project principals until ethics approval for the project has been obtained and a copy of the approval is on file in the Vice-Chancellor's Office.

3. Research Ethics Committee [REC]

3.1 The REC is a sub-committee of the Academic Council. It is responsible for the timely review of all research protocols or projects covered by this Policy to ensure that they meet acceptable ethical standards.

3.2 The REC has the authority to approve a protocol or project, approve a protocol or project subject to modifications, or reject a protocol or project. In the latter two cases, detailed written reasons will be provided to assist researchers in the preparation of revised applications for ethics approval.

3.3 The REC has the responsibility to monitor on-going research and to terminate any project that does not conform to ethical standards.

3.4 The REC is responsible for responding to inquiries from external agencies with responsibility to monitor ethics review procedures at universities.

3.5 Prior to serving, all members of the REC will attend a workshop or orientation session, organized by the Vice-Chancellor's Office, to ensure that they have an understanding of the principles and practices of ethical review. The workshop requirement may be substituted by the on-line tutorial accessed at http://www.pre.ethics.gc.ca/english/tutorial or a similar tutorial approved by the REC.

3.6 On an annual basis, the REC will elect a Chair and a Deputy Chair who will act in the absence of the Chair. These persons will

a. be responsible for research ethics education programs at IUBAT;
b. assist researchers in the preparation of applications for submission to the REC;
c. review all applications submitted to the REC for the completeness of these applications and their compliance with this Policy;
d. advise the REC with respect to the category of risk (i.e., minimal, in-course student, or non-minimal) of an application;
e. approve minimal risk applications, and provide summaries of such approvals to the REC;
f. prepare a report on the disposition of each proposal at the REC.

4. **Risk Analysis**

4.1 Researchers should assess all reasonably foreseeable risks involved in, and benefits expected to arise from research projects. Researchers involved in greater than minimal risk research projects should be prepared to document reasonably foreseeable risks and benefits.

4.2 Researchers should employ methods that avoid or reduce possible risks, and maximize benefits in keeping with disciplinary and epistemological norms and standards.

4.3 Researchers should consider potential risk of:

a. physical harm to the participants or third parties;
b. psychological harm to the participants or third parties;
c. injury to reputation or privacy of the participants or third parties;
d. breach of any applicable law;
e. harm to any community.

5. **Informed Consent**

5.1 Informed consent may be obtained in different ways:

a. **expressed opt-in** by written, oral or by the conduct of the participant, such as returning a questionnaire. This type of consent must be voluntary, informed, unambiguous, obtained before beginning the research and may be withdrawn at any time, and unless there is explicit consent at the time of data collection, there will be no further collection of additional data, no further analysis of the data initially collected and there will be removal of the data from the database to the extent possible;
b. **implied**, which must be voluntary, with opt-out provisions where consent is assumed because the participant does not opt out. Participants may be notified of the research in writing by various means, including brochures, letters, media, announcements and advertisements of the research and of the provisions for opting out. Opt-out opportunities include written, oral or conduct, such as leaving the research site;
c. **oral**, which is acceptable where written documentation is culturally unacceptable, or where there are good reasons for not recording opt-in or opt-out in writing, using a form that the participant signs. An oral procedure should be managed and documented, indicating how the opt-in and opt-out provisions were conducted;
d. When research participants desire anonymity and personal data can be collected without the researchers present (such as the use of a self-administered questionnaire) individuals could indicate consent by filling out and mailing back an anonymous questionnaire to the researcher. Documentation of the consent should be done separately in order to prevent linking research participants to their data or the results of analyses.

5.2 Normally, researchers must provide the following information to participants or authorized third parties:

a. information that the subject is being invited to participate in a research project;
b. an understandable description of the research goals, the identity and institutional affiliation of the researcher, contact information, the duration, the nature of participation, and a description of research procedures;
c. an understandable description of reasonably foreseeable harms and benefits that may result from participation as a research subject;
d. an assurance that participants are free to avoid participation or to withdraw from participation at any time;
e. prior to conducting research activities and where applicable, participants must be advised whether employers, and/or government agencies have *given permission, denied permission, or have not been approached for permission*, to include their employees to take part in the study.

5.3 Individuals who are not legally competent, or who are under legal guardianship, or who are members of a captive population may be asked to become research subjects only if all the following conditions are satisfied:

f. the research requires the participation of such individuals;
g. free and informed consent will be obtained from participants competent to do so and for those who are not, from their legally authorized representatives;
h. research is in the "minimal risk" category, or has the potential to provide distinct benefits to the research subjects;
i. the researcher can show how the subjects' best interest will be protected.

6. International Projects

When a protocol requires collaboration with universities, agencies or individuals in other countries:

a. The REC, in conjunction with the Vice-Chancellor's Office, shall normally require confirmation by the collaborating universities, agencies or individuals of compliance with the IUBAT Policy as part of any contract between IUBAT and the collaborating university, agency or individual;
b. The REC may review the protocols and responsibility of those international universities, agencies or individuals;
c. The REC may accept the decision of an international university, or agency as a substitute for their own review if the procedures adopted by that university, agency or individual comply with IUBAT policy.