

# Brandon University Research Ethics Committee (BUREC) Guidelines For Research Involving Humans

Revised 03/2003

In March 1999, the Brandon University Senate adopted the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* as its policy for research involving human subjects. The Brandon University Research Ethics Committee (BUREC) follows the *Tri-Council Policy Statement*, the BUREC Guidelines approved by Senate (June 10, 1997), and the principles outlined in the *Brandon University Policy on Academic Integrity in Research, Scholarship and Creative Activity*.

This document provides a **brief overview** of the major issues that arise in the ethics of research involving humans. It is the responsibility of the investigator to satisfy BUREC that relevant conditions of the research have been addressed. Please consult relevant sections of the *Tri-Council Policy Statement* for additional information.

## Guiding Ethical Principles

Researchers are reminded that the *Tri-Council Policy Statement* is based on a framework of guiding principles for conducting research in various disciplines: *Respect for Human Dignity, Respect for Free and Informed Consent, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality, Respect for Justice and Inclusiveness, Balancing Harms and Benefits, Minimizing Harm, and Maximizing Benefit* (p. i.5).

### Minimal Risk

"The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects" (*Tri-Council Policy Statement*, p. 1.5).

## Brandon University Research Ethics Committee (BUREC)

BUREC is a sub-committee of the Senate Research Committee. Its composition and responsibilities are set forth in *The Bylaws of the Senate of Brandon University*.

The membership of BUREC comprises:

- (a) a chair to be appointed by the Senate Research Committee
- (b) one faculty member who is knowledgeable in ethics to be appointed by the Senate Research Committee from among names submitted by the Deans to the Office of the Vice-President (Academic and Research)
- (c) two faculty members with broad expertise in research involving humans, to be appointed by the Senate Research Committee from among names submitted by each

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(d) one person who is knowledgeable in ethics, but who has no affiliation with the University, to be appointed by the Senate Research Committee

Members of BUREC are appointed for three-year (renewable) terms with the exception of the initial appointments, which are staggered to provide continuity.

### **Review Procedures**

Research involving any potential harm to participants requires careful consideration by BUREC. BUREC will establish and communicate a regular schedule of meetings. Researchers will provide BUREC with sufficient information for a full ethics review (see *BUREC Checklist for Projects Involving Human Participants in Research* available on the web-pages of the Brandon University Research Office). It is the responsibility of researchers to maintain appropriate ethical standards in conducting research throughout the extent of the project and in the reporting and presenting results. It is also the investigator's responsibility to maintain appropriate ethical standards and procedures in the scientific and professional activities of assistants, students, supervisees, and employees.

### **Record Keeping**

Minutes of all BUREC meetings will be prepared and maintained on behalf of BUREC by the Research Office. These minutes will clearly document the Committee's decisions and any dissents and reasons.

### **Conflict(s) of Interest**

If BUREC reviews research in which a Committee member has some personal interest (e.g., as a researcher or as an entrepreneur), conflict of interest principles dictate that the member **not** be present when BUREC is discussing and making its decision.

Researchers have the right to request, and BUREC has an obligation to provide, reconsideration of decisions affecting a research project. In cases where the researcher and BUREC cannot reach an agreement through discussion and reconsideration, the researcher may request that the application be reviewed by an appeals committee. Brandon University and the University of Winnipeg have entered into a formal agreement whereby the Research Ethics Board (REB) of one institution will serve as the Ethics Review Appeals Committee for the other institution.

### **Review of Ongoing Research**

Ongoing and continuing ethical review is required in accordance with the principle of proportionate review. The minimum requirement is the submission of an annual status report to BUREC and prompt notification when the project is completed. In addition to annual review, ongoing review of research might include, for example, the reporting of adverse events and the operation of a psychological safety net, etc. (refer to Article 1.13 of the *Tri-Council Policy Statement*).

# Research Requiring Ethics Review

All research proposals involving humans must be approved by BUREC prior to the commencement of any research activities. Proposals involving animals must be approved by the Brandon University Animal Care Committee (BUACC). Biomedical protocols must be submitted to BUREC, which will in turn forward them to the University of Manitoba for review and approval by their Biomedical Research Ethics Board.

The *Tri-Council Policy Statement* sets out the basic elements that determine whether research involving human subjects should undergo ethics review before research begins. First, the undertaking must involve "research," which involves a systematic investigation to establish facts, principles or generalized knowledge. Second, the research must involve living individuals as "research subjects." However, ethics review is generally not required for research involving public policy issues, the writing of modern history, or literary or artistic criticism, even though all of these might well involve human subjects. Data gathered from archival or other sources routinely available to the public are also normally exempt. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Ethics review is required only if the subject is approached directly for interviews or access to private papers (Article 1.1a).

"Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review" (*Tri-Council Policy Statement*, p. 1.1)

## Scholarly Review as Part of Ethics Review

Brandon University is a small university and, therefore, BUREC has adopted the following procedures in order to avoid the duplication of peer review assessments:

### *Faculty Research*

- Externally Funded Faculty Research Projects are provisionally reviewed by BUREC (e.g., potential harm or benefit) and, if satisfactory, *approved in principle* pending peer review by the external agency. Full ethical review is undertaken if the project is subsequently approved for funding.
- Internally Funded Faculty Research Projects are of two general types, that is, those awarded funds by the Brandon University Research Committee (BURC) and those that receive funds from other internal sources:
  - a) BURC-funded projects must be submitted to and approved by BUREC prior to the consideration of their scholarly merits by BURC. Hence, eligibility for research awards is dependent upon ethical and scholarly review by BUREC and BURC.
  - b) Non-BURC-funded projects should be reviewed by a Faculty committee for their scholarly merits and then forwarded to BUREC for ethical approval.
- Unfunded Faculty Research Projects which fall within the mandate of BUREC and are financed either privately or through an individual's Professional Development Allowance

(P.D.A.) must be approved by BUREC before the research can commence.

### *Graduate and Undergraduate Student Research*

Research methods courses in various disciplines, especially at the graduate level, should include the topic of research ethics.

In many instances, students are required to do research projects as part of their curriculum. Often these projects have more to do with research training than original scientific research. When students are required to do research with human subjects as part of their curriculum, subjects must be informed that the research enterprise is undertaken for training purposes.

Ethical approval from BUREC is required for graduate and undergraduate research involving humans. The Research Ethics Committee will take into consideration the special nature of these projects in relation to ethics. The usual ethical standards must be maintained.

· Graduate Student Research Projects and Theses: Graduate student research projects and theses are reviewed by BUREC in order to assess the ethical issues of the projects. Proposals must be approved by the project or thesis committee before being submitted to BUREC for ethical review. Suggestions concerning ethical aspects of the proposed research activities will be forwarded to the student and the supervising faculty member.

· Undergraduate Student Research Projects. Fourth-Year Undergraduate Student Research Activities, Specialist Theses, and Topics Course Projects involving human subjects are to be screened by a three-person faculty subcommittee of BUREC consisting of one member of BUREC, the student's instructor, and another faculty member selected by BUREC. The BUREC representative will report back to the full Committee.

· Undergraduate Class Research Projects. Course-based research projects are vetted through BUREC according to the guidelines (e.g., minimal risk) set out in the attached *BUREC Procedures for Using Human Participants for Teaching Students About Research in Class Projects*.

### **Proportionate Approach to Ethics Review**

BUREC reviews projects on a proportionate basis that takes into consideration the potential harm or risk and the invasive nature of the research. The following list illustrates the approximate levels of (ascending) harm or risk involved:

1. Undergraduate Class Research Projects that pose only minimal risk must follow the *BUREC Procedures for Using Human Participants for Teaching Students About Research in Class Projects*.
2. Undergraduate Student Research Projects involving human subjects are screened by a BUREC subcommittee (see above).
3. Externally Funded Faculty Projects are first subjected to expedited ethical review and, if found satisfactory, given *approval in principle* pending peer review by the external agency.
4. Full ethical review is required of *all* research involving human subjects: Externally Funded Faculty Research Projects approved for funding, Internally Funded (i.e., BURC

and non-BURC) Faculty Research Projects, Unfunded Faculty Research Projects, and Graduate Student Research Projects.

### **Informed Consent**

Informed consent must be obtained from participants prior to the onset of data collection. This involves the use of: (a) signed informed consent forms which specify the dimensions of informed consent (see Brandon University Research Office web-pages for *Sample Consent Form*); or (b) participants' acknowledgment that such dimensions have been explained and are understood by the person(s) giving consent.

· Informed consent requires that the researcher insure that participants are aware of:

- a) the purpose of the research;
- b) the name of the researcher(s) and collaborating parties;
- c) potential benefits;
- d) tasks to be performed by participants;
- e) any anticipated inconveniences to participants;
- f) rights of participants including:
  - i) the right to refuse or withdraw at any time;
  - ii) the right to confidentiality of personal information;
- g) potential harms involved;
- h) the time period over which consent applies;
- i) how to rescind consent.

**NOTE: A *Checklist for Projects Involving Human Participants in Research* is available on the web-pages of the Brandon University Research Office.**

· The investigator must convey information related to informed consent in language that the person understands (including translation into another language, if necessary) and take whatever reasonable steps are necessary to assure that the information is understood.

· Consent must be completely voluntary, that is, it must not be elicited under any condition of coercion or pressure.

· The researcher must not offer rewards sufficient to motivate an individual or group to participate in an activity that has known possible risks to participants.

· Informed consent must be obtained from those persons who are legally responsible or appointed to give informed consent (e.g., parents and guardians) on behalf of individuals who are under the legal age and/or who are not able to provide informed consent. Assent must also be obtained from the participants themselves, including children and adolescents under the legal age.

· In order to obtain informed consent from persons of diminished capacity, the researcher is required to explain the purpose of the study as well as possible and to proceed without this *only* if the researcher has received prior approval from BUREC.

- Deception or partial disclosure of information can be used only when BUREC is satisfied that the appropriate conditions are met.

### **Anonymity and Confidentiality**

- The investigator must inform the participants concerning the measures that will be taken to protect anonymity and confidentiality.
- Confidential information may be presented or shared with others only with the informed consent of those involved or in a manner that the individuals involved cannot be identified.
- It is important to clarify to participants if and how the research findings will be shared with third parties.

### **Data Collection, Handling, and Retention**

- Data collection should be restricted only to information which is germane to the purpose (s) for which consent has been obtained.
- The researcher must store, handle, and transfer all records, both written and unwritten (e.g., computer files and videotapes), in a way that attends to the needs for privacy and security. This would include having adequate plans for destroying or safeguarding records in circumstances of one's own serious illness or demise.
- Researchers must take all reasonable steps to ensure that records over which they have control remain personally identifiable only as long as it is necessary and render anonymous or destroy any records no longer needed.
- Researchers are required to retain and to store securely all forms of collected data (e.g., completed questionnaires and computer data sets) for a period of no less than five years after the completion of the project.

### **Special Populations**

The investigator must be sensitive to cultural and life cycle variations regarding privacy, confidentiality, and customs when working with vulnerable populations, ethnic minorities, and when conducting research in other countries.

### **Multi-centred Research**

"Principles of institutional accountability require each local REB to be responsible for the ethical acceptability of research undertaken within its institution. However, in multi-centred research, when several REBs consider the same proposal from the perspectives of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research. To facilitate coordination of ethical review, ... , the researcher may wish to distinguish between core elements of the study research -- which cannot be altered without invalidating the pooling of data from participating institutions -- and those elements that can be altered to comply with local requirements without invalidating the research project" (*Tri-Council Policy Statement*: p. 1.11).

### **Research in Other Jurisdictions or Countries**

All research conducted outside of the jurisdiction of Brandon University or outside of Canada must undergo ethical review both by (a) BUREC and (b) "by the REB, where

such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done" (*Tri-Council Policy Statement*, p. 1.12). BUREC will take into consideration the safety of both the research subjects and the researchers. The plans for maintaining anonymity, confidentiality, and security of research materials will also be carefully assessed. Researchers should ensure that the benefits of their research are made available to the participants and/or appropriate agencies.

### **Naturalistic Observation**

"REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility" (*Tri-Council Policy Statement*, p. 2.4)

"Naturalistic observation is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the subjects do not know that they are being observed, and hence can not have given their free and informed consent. Due to the need for respect for privacy, even in public places, naturalistic observation raises concerns of the privacy and dignity of those being observed. These concerns are accentuated if, for example, the research records permit identification of the subjects, or if the research environment is staged" (*Tri-Council Policy Statement*, p. 2.5).

Careful consideration is required for the ethical implications of such factors as: "the nature of the activities to be observed; the environment in which the activities are to be observed (in particular, whether it is to be staged for the purposes of the research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the subjects). Naturalistic observation that does not allow for the identification of the subjects, and that is not staged, should normally be regarded as of minimal risk" (*Tri-Council Policy Statement*, p. 2.5).

### **Research in Emergency Situations**

Subject to all applicable legislative and regulatory requirements, research involving emergency situations shall be conducted only in accordance with criteria established in advance for such research with BUREC. BUREC may approve research that involves emergency situations (e.g., disasters) to be carried out as long as informed consent of the subjects (or of authorized third parties) is acquired. Careful review of the harms and benefits will be undertaken to ensure the safety, rights, and welfare of research subjects.