



## **Bishop's University Research Ethics Policy**

Approved by Senate on May 11, 2001 and revised in 2003, 2011, 2012 and 2018

### **Preamble**

Bishop's University endorses the principles set out in the Tri-Council Policy Statement (TCPS2) [\*Ethical Conduct for Research Involving Humans\*](#) (2010) and this document describes how Bishop's will apply TCPS2

Research is an essential component of the mission of the University and some of this research involves studying human participants. The University has a responsibility to engage in research advancing human knowledge. The use of human beings in the conduct of research confers responsibilities to the investigator(s). It is also the responsibility of the University to promote the awareness and training of ethical research.

This policy is intended to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at the University in compliance with the TCPS2. These ethical standards include Respect for Humans, Concern for Welfare, and Justice. It is crucial that the REB function independently in order to fulfill its responsibilities and to ensure that all core ethical standards are respected.

Ethics review and approval is available normally only to projects in which members of the University's research community are involved. Should members of the University's research community be conducting research with multiple institutions, they should refer to section 1.4 of this policy. The term "Research" is understood as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. A fundamental premise of this policy is recognizing the importance that academic freedom holds in pursuit of the wide varieties of research that have greatly improved and enriched our lives. Among the many rights and responsibilities related to academic freedom, this policy holds in great value the assurance that research involving humans meets high scientific and ethical standards that respect and protect the participants.

This policy requires that all research projects involving human participants undertaken by members of the university community — including all faculty, staff and students — fall within the jurisdiction of the Research Ethics Board (REB), irrespective of the source of financial support (if any) and irrespective of the location of the project, in the latter case so long as the investigator represents the work as Bishop's research. Review and approval by the Research Ethics Board is also necessary for human remains, cadavers, tissues, biological fluids, etc., taken in routine situations but which are later used for educational and research purposes. If human participants are involved in a teaching exercise (i.e., part of an undergraduate or graduate course and/or Honour's project), and entail no more than minimal risk, it must be reviewed and approved by the Ethics

Review Committee for Student Research on behalf of the REB and in compliance with the TCPS2. Certain forms of research do not require REB approval. Research involving naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings would not require Research Ethics Board review and approval if it can be expected that the participants are seeking public visibility. Other examples would include using publicly accessible information and program evaluation policies. For a complete list of research that is exempt from the REB, please refer to articles 2.2 to 2.6 in the TCPS2.

Research governed by this Policy may begin only if prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation (see Guidelines for Consent Forms); and their free and informed consent has been given and is maintained throughout their participation in the research. It should be noted that following the initial REB, research ethics review shall continue throughout the life of the research project in accordance with regulations provided in the TCPS 2.

## **1. Terms of Reference**

### **1.1 Responsibilities**

The University's Research Ethics Board (REB) is responsible to the highest body within Bishop's University (The Senate) for:

- Developing policies regarding ethical issues relating to the use of human participants in research and experimental teaching protocols;
- Reviewing and approving all protocols requiring the participation of human participants for ethical approval;
- Reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;
- Dealing with matters concerned with human-based research referred to the REB by The Senate of Bishop's;
- Preparing an annual report for submission to The Senate;
- Coordinating the Ethics Review Committee for Student Research;
- Recruiting, nominating, and training members of the REB and Ethics Review Committee for Student Research who have the proper skills and experience to fulfill their responsibilities;
- Organizing continuing education activities for REB and Ethics Review Committee for Student Research members in matters relating to ethics and the use of human participants.

The policies and practices adopted by Bishop's REB will be consistent with the TCPS2.

Notwithstanding the second bullet point above, where a multi-centered research project:

- ◆ Entails minimal risk within the meaning of the TCPS2; and

- ◆ Involves both members of the Bishop's University community and a Principal Investigator at a Quebec university which is a party to the *Entente pour la reconnaissance des certificats d'éthique des projets de recherche à risque minimal* (the 'Entente');

The review and approval of research protocols shall be undertaken by the Research Ethics Board for the university under whose auspices the Principal Investigator carries out research.

Where research protocols are approved by the Research Ethics Board of another Quebec university under the *Entente*, Bishop's University shall recognize the certificate of approval unless our Research Ethics Board determines that the research entails more than minimal risk within the meaning of TCPS2.

## **1.2 Composition of REB**

Composition of the REB shall be nominated by the existing REB and approved by The Senate. At the end of each academic year, and foreseeing upcoming vacancies in the REB and/or Ethics Review Committee for Student Research, the REB will issue a call for nominations specifying the TCPS2 mandated requirements in terms of knowledge and expertise required in relevant research disciplines (article 6.4), as determined by the particular needs of the committee at that time. This call will be public and all interested faculty members will have a chance to apply. Decision on such nominations will then be reached by the REB committee.

The REB shall be made up of no less than 5 members and include at least:

- One community representative with no formal affiliation with the University, approved by The Senate for a two-year term and selected in accordance with TCPS2;
- An individual knowledgeable in the relevant law, with no formal affiliation with the University, approved by The Senate for a two-year term and selected in accordance with TCPS2;
- Two faculty members with expertise in the methods of research involving human participants or the use of human tissue, approved by The Senate for two-year terms;
- One faculty member with broad knowledge in ethics or experience in the evaluation of ethical implications of research involving human participants, approved by The Senate for a two-year term.

One non-voting representative from the Research Office will serve *ex officio* on the REB.

The REB shall require a quorum of fifty percent plus one and relevant expertise in attendance at all meetings concerned with ethics review and approval of research proposals.

Approved by The Senate, the established REB shall appoint the Chair and determine the length of term for the Chair.

For research within specialized areas or methods, the REB can ask that an external, specialized or multi-institutional REB review the application, where such bodies exist. These specialists will provide specific information to help members of the REB establish quorum.

### **1.3 Meetings and Decision-making**

The REB shall meet monthly during the fall, winter and spring sessions and as needed during the summer semester to review and approve all research protocols requiring the participation of human participants. The REB may also meet when a particular situation requires it. Decisions to grant ethical approval must be based on a vote and will require at least three votes to carry. If a vote is not unanimous, the position of those disagreeing will be included in the communication to the researcher. In the event of a tie vote, the matter under consideration will be considered not passed.

Where, under s. 3.3 of the *Entente*, a Research Ethics Board at another Quebec university has communicated a certificate of approval and a summary description of a multi-centered research project in which one or more members of the Bishop's community are participating, the chair of the Research Ethics Board of Bishop's University shall bring the approval to the attention of the full Board at the first available opportunity.

The Research Ethics Board of Bishop's University shall accept the certificate of approval, unless it determines, on the basis of the certificate of approval and summary description that the research project entails more than minimal risk within the meaning of TCPS2. The Bishop's Research Ethics Board will carry out a review and approval process only where it has determined that the project entails more than minimal risk. This process shall apply only to members of the Bishop's research community.

Notwithstanding a decision by the Research Ethics Board of Bishop's University that a research project involves minimal risk, the certificate of approval issued by the Research Ethics Board of the University under whose auspices the Principal Investigator carries out research will apply to the work of the Principal Investigator as well as to all investigators at other universities whose Research Ethics Boards deem the project to entail minimal risk.

An annual schedule of REB regular meetings will be published every August 31.

### **1.4 Authority**

The University endorses the ethical principles cited in the TCPS2 and has mandated its Research Ethics Board (REB) to ensure that all research investigations involving human participants are in compliance with the Statement.

Bishop's REB will have jurisdiction over all research involving human participants (including stopping research not in conformity with agreed ethical principles or the TCPS2). Research involving human participants will proceed ONLY following ethics review where approval has been granted by either the REB or by the appropriate Ethics Review Committee for Student

Research (see below). An exception to this policy concerns certain multi-centered research projects entailing minimal risk as set forth below.

Where:

- ◆ one or more members of the Bishop's University research community participate in a multi-centered research project with investigators from at least one other Quebec university that is a party to the *Entente*; and
- ◆ the Principal Investigator carries out research under the auspices of a Quebec University that is a party to the *Entente*; and
- ◆ the research project involves minimal risk within the meaning of TCPS2; and
- ◆ a certificate of approval and a summary description of the research are issued by the Research Ethics Board of the university under whose auspices the Principal Investigator carries out research,

Bishop's University and the Bishop's Research Ethics Board will normally recognize the certificate and accept the approval.

## **2. Procedural Guidelines for the Review and Approval of a Research Proposal**

### **2.1 Submission**

The basic principle is that ethical review and approval of all "Bishop's research" (as defined in the Preamble) comes under the jurisdiction of the REB. This refers to research involving human participants undertaken by members of the university community — including all faculty, visiting researchers, students, and staff — irrespective of the source of financial support (if any) and irrespective of the location of the project. While it is not necessary for the REB to review a proposal before it is submitted to a funding agency, REB approval must be obtained before the work begins. Visiting researchers should contact the Bishop's REB well in advance of the anticipated start date of research. Submissions for review and approval should be submitted to the Bishop's REB using the "Ethics Submission Form for Research Involving Human Participants".

Where one or more members of the Bishop's research community participate in a multi-centered research project that entails minimal risk within the meaning of TCPS2 and the Principal Investigator on the project is located at a Quebec university that is a party to the *Entente*, the review and approval of research protocols shall be undertaken by the university under whose auspices the Principal Investigator carries out research.

For externally-funded research scholarly review will be assessed by the appropriate external agency; for internally-funded research scholarly review will be assessed by The Senate Research Committee; for unfunded research scholarly review shall be conducted by the REB at its meetings.

Not legally competent individuals can be included in a research project only when:

- The research question can only be addressed using individual within the identified group (s); and
- Free and informed consent will be sought from their authorized representatives; and
- The research does not expose them to more than minimal risks without the potential for direct benefits for them.

To obtain informed consent from not legally competent participants:

- The researcher shall show how the free and informed consent will be sought from the third party, and how the subject's best interests will be protected;
- The authorized third party may not be the researcher or any other member of the research team;
- The continued free and informed consent of an appropriately authorized third party will be required to continue the participation on a legally incompetent participant in research, so long as the subject participant remains incompetent;
- When a participant who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

Where free and informed consent has been obtained from an authorized third party and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

## **2.2 Ethics Review and Approval**

The effective working of ethics review and approval — across the range of disciplines conducting research involving human participants — requires a reasonable flexibility in the implementation of common principles. This policy, therefore, seeks to express the shared principles and wisdom of researchers in diverse fields. The following standards and procedures will be used by the REB for ethics review and approval:

(a) All research that involves living human participants requires ethics review and approval by the REB in accordance with this policy, before the research is started, except as stipulated below.

(b) Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses should also be reviewed and approved by the REB. Review by the REB is also necessary for such materials taken in routine situations but which are later used for educational purposes.

(c) Research about an 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 and approval. Research involving primary interviews where the questions pertain strictly to the individual's professional career is also exempt from the review/approval process. However, if the interview has the potential to elicit personal information having no professional relevance or if access to private papers is requested, then ethics review and approval is required to ensure that such approaches are conducted according to professional protocols.

(d) Quality assurance studies, performance reviews or testing within normal educational requirements will not be subject to review and approval.

(e) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labor, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

(f) Naturalistic Observation: Naturalist (or “non-participant”) observation is used to study behavior in a natural environment. Because knowledge of the research can be expected to influence behavior, naturalistic observation generally implies that the human participants do not know that they are being observed, and hence cannot 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 human participants, or if the research environment is staged.

In considering research involving naturalistic observation, researchers and the REB should pay close attention to 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 human participants). Naturalistic observation that does not allow for the identification of the human participants, and that is not staged, should normally be regarded as of minimal risk.

(g) In the case of research being carried out in First Nations, Inuit and Métis Peoples of Canada, as well as with participants associated with indigeneity, the standards established in chapter 9 of the TCPS2 will be applied.

### **2.3 Ethics Review and Approval of Multi-Centred Research**

The REB shall review and approve all research proposals as long as the investigator represents the work as Bishop’s research, regardless of the location where the research is conducted. In multi-centred research, the researcher may wish to distinguish between core elements of the research (which cannot be altered without invalidating the pooling of data from the participating institutions) and those elements that can be altered to comply with local requirements without invalidating the research project.

Notwithstanding the above, where:

- ◆ one or more members of the Bishop’s University research community participate, jointly with investigators from at least one other Quebec university that is a party to the *Entente*, in a multi-centred research project that entails minimal risk within the meaning of TCPS2; and

- ◆ the Principal Investigator on the research project is located at a Quebec university that is a party to the *Entente*; and
- ◆ a certificate of approval and a summary description of the research are issued by a Research Ethics Board of the university under whose auspices the Principal Investigator carries out research,

Bishop's University and the Bishop's Research Ethics Board will normally recognize the certificate and accept the approval. Where the certificate is accepted, no further review process shall be carried out by the Research Ethics Board of Bishop's University.

#### **2.4 Ethics Review and Approval of Research Performed during Publicly Declared Emergencies**

Publicly declared emergencies are extraordinary events that arise suddenly or unexpectedly, and require urgent or quick responses to minimize devastation. The REB will put into place policies to establish protocols in such emergency situations. The REB will collaborate in the review and approval of Research Performed during publicly declared emergencies with the relevant research ethics committee (if applicable) where the work is to be conducted. (Please see section 6.21 – 6.23 of the TCPS2 for complete details)

#### **2.5 Review and Approval of Student Research**

If human participants are involved in a teaching exercise (i.e., part of an undergraduate or graduate course, class activity or assignment and/or Honour's project), and entail no more than minimal risk, it must be reviewed and approved by the Ethics Review Committee for Student Research on behalf of the REB and in compliance with the TCPS2. The composition and procedures of the Ethics Review Committee for Student Research will be coordinated by the university-wide REB. The Ethics Review Committee for Student Research must report results of such reviews and approvals to the REB at the end of the academic year.

Student research deemed to be beyond minimal risk and all Master's thesis involving human participants must be reviewed and approved by the REB.

#### **2.6 Principle of Proportionate Review**

The REB will use a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in undertaking ethics review and approval.

#### **2.7 Normal Review and Approval Process**

The REB shall normally meet face to face in order to review and approve submitted research proposals. The REB may meet face to face with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but not be present when the REB is making its decision. Minutes will be kept for these meetings.

Researchers will apply for ethical review and approval to the Research Office where their files will be kept. A file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review and approval process. It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up to date at all times. When the research project is finished, and the researcher(s) notifies the Research Office and the Bishop's REB, these files shall be "closed" and kept as records demonstrating compliance with the TCPS2. The files remain the property of Bishop's and cannot be removed from the Research Office by the researchers. These files shall be subject to audit by authorized representatives of Bishop's (research administrators), members of Appeal Boards, and funding agencies.

All research receiving REB review and approval, as well as that receiving approval from the Ethics Review Committee for Student Research, shall require a proper file showing compliance with the TCPS2. Insufficient information in the file is grounds for refusing or delaying ethical approval.

### **2.8 Continuing Ethics Review and Approval**

(a) Ethical Approval, signed by the Chair of the REB will be issued to the Principal Investigator(s) and copies sent to the Research Office.

(b) Any decisions by the Chair to approve minor amendments without full committee review will be reported to the committee at the next scheduled meeting.

(c) Ongoing research shall be subject to continuing ethics review and approval. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers will be asked to include monitoring mechanisms by which the public participating in the research may contact the Chair of the REB. Problems or complaints will be taken seriously by the REB and researchers may be asked to modify their studies in view of such complaints.

(d) An ethics approval is issued for the term of the intended research. If a project continues after stated duration the researcher must re-submit. Any significant changes or unforeseen complications should be promptly brought to the attention of the REB Chair for review. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue an appropriate extension. If in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, ethics review and approval by the REB is required.

(e) The REB or the Ethics Review Committee for Student Research shall be promptly notified by the applicable researchers when the project concludes. Research completion forms can be found on the REB website.

### **3. Decisions of the Research Ethics Board**

### **3.1 Reconsideration**

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Bishop's may not override negative REB decisions reached on grounds of ethics without a formal appeal mechanism.

### **3.2 Appeal**

Researchers must appeal a negative REB decision within two weeks of the date of the decision. To do so the researcher must send an appeal letter to the Research Office with a copy to the REB Chair. The appeal letter shall be sent by the Research Office to the appropriate REB at Université de Sherbrooke or University of Prince Edward Island, which is going to act as the appeal board. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS2. The decision of the Appeal REB shall be final.

## **4. Report of the Research Ethics Board**

An annual activity report from the REB will be made to The Senate for its consideration. This report will include a list of the multi-centred research projects for which protocols were approved under the *Entente* by the Research Ethics Board of another Quebec university, indicating:

- ♦ the name of the University,
- ♦ the name of the Principal Investigator, and,
- ♦ where the University has more than one Research Ethics Board, the name of the Board that reviewed and approved the protocols.

## **5. Administration**

### **5.1 University and Administrative Support**

The work involved in the ethical review and approval process should be distributed appropriately among faculty members, staff, researchers, and administrators.

The Research Office will provide administrative support to the REB including:

- (a) Distribution of forms and materials necessary for submission of research proposals to the REB;
- (b) Collection of submissions and distribution of submissions to REB members;
- (c) Keeping minutes of REB meetings;
- (d) Storing submissions and related materials in a secure location;

- (e) Supporting the REB in its educational activities;
- (f) Acting as the point of contact for the Tri-Council Panel on Research Ethics;
- (g) Other duties related to the support of the REB in carrying out its mandate.

Deans of Faculties and Schools will provide significant support to the REB, with respect to:

- Ensuring that researchers requiring ethical review and approval are submitting their projects to the REB;
- Advising their faculty members about the need to comply with the TCPS2.

Individual departments are expected to support and train students so that undergraduate and graduate research projects are ethical, and those that exceed minimal risk may be efficiently reviewed and approved by the REB. Undergraduate and graduate research deemed at the outset to be above minimum risk should be submitted to the REB. The Ethics Review Committee for Student Research should screen all other student applications for ethical review and approval and when protocols are believed to be above minimum risk, forward the submission to the REB.

## **5.2 Sanctions**

Upon recommendation of the REB, the Associate Vice-Principal Research shall have the sanction of refusing permission to open a research account or access university-controlled funds for researchers who do not comply with the TCPS2.

The REB will report to the Principal any cases that undermine Bishop's compliance with the TCPS2.

## **6. Acknowledgement**

In preparation of the Research Ethics Policy, the TCPS2: Ethical Conduct for Research Involving Humans (2010) and the UPEI Research Ethics Policy were consulted.