Policy Statement Research Ethics Board St. Francis Xavier University

Preamble

In August, 1998, a policy statement was issued jointly by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada (hereafter referred to as the Tri-Council) entitled *Ethical Conduct for Research Involving Humans*. As a condition for continued funding from these three Councils, each Canadian university was required to establish at least one Research Ethics Board (REB) that would function in accordance with the guidelines contained in the Tri-Council's policy statement.

Purpose

In Accordance with the Tri-Council policy statement (2014), the purpose of St. Francis Xavier University's REB is "...to review the ethical acceptability of all research involving humans conducted within [its] jurisdiction or under [its] auspices, that is, by... faculty, staff or students...."

1.0 Terms of Reference

- 1.1.1 The mandate of the University's Research Ethics Board is to review, from an ethical perspective, all research conducted by members of the University community that involves human participation.
- 1.1.2 Review is also required for research involving human remains, cadavers, tissues, biological fluids, etc., and includes samples taken in routine (for example, training or diagnostic) situations that will be used later for research purposes.
- 1.2.1 The REB's mandate includes the right to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted by faculty, staff, or students of St. Francis Xavier University based—as a minimum standard—on the considerations set forth in the above mentioned Tri-Council policy statement (2014).
- 1.2.2 Review is also available to researchers who are members of the University community and who are pursuing research in formal collaboration with those not affiliated with the University.
- 1.3.1 The REB's mandate applies to research that is:
 - a. funded by one or more of the Tri-council members;
 - b. funded by any other external or internal funding body:
 - c. "self-funded"; or
 - d. unfunded.
- 1.3.2 This mandate applies to research of the relevant type, whether or not it is to be undertaken at St. Francis Xavier University.
- 1.4.1 In accordance with the Tri-Council policy, all undergraduate honours projects involving research with human participants will have to be approved through the StFX REB. The StFX REB will operate in close consultation with the Departmental, School, or Program REBs so that projects may be reviewed as

- efficiently as possible. Course-based research will continue to be reviewed by Departmental, School, or Program REBs.
- 1.4.2 All Departments, Schools, and Programmes where research involving human participants is done by three or more students in any year as part of honours theses, advanced majors' senior papers, or as part of student course work (including laboratory components of courses) shall establish an ethics committee as a standing committee.
- 1.4.3 In Departments, Schools, and Programmes where fewer than three students are annually involved in such research, ad hoc ethics committees shall be established as required.
- 1.4.4 The Chair of the Department, School, or Programme's ethics committee shall report annually in writing to the Chair of the REB, listing the names of the researchers and their projects.
- 1.4.5 The University REB has the responsibility to ensure that departmental ethical review procedures comply with the Tri-Council policy statement in terms of ethical evaluation and record keeping.
- 1.5.1 The adoption and implementation of the Tri-Council policy statement shall not be used to circumscribe the academic freedom of researchers.
- 1.5.2 These freedoms include, but are not limited to, the freedom of inquiry and right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the freedom to conduct research involving human participants deemed ethical by the REB.
- 1.6 Notwithstanding Section C2, Article 1.5 of the Tri-Council policy statement, the REB only has the power to review the ethics of research involving humans in accordance with the Tri-Council policy statement.
- 1.7 The REB does not have, nor shall it assume, the ability to reject any proposal on the grounds of either its perceived scholarly merit or its pedagogical appropriateness.
- 1.8.1 The REB does not have, nor shall it assume, the power to: recommend discipline, impose sanctions or discipline, or to cause discipline to be imposed upon members of the University's research community.
- 1.8.2 The REB, however, has the responsibility to bring to the attention of the appropriate University administrator or body concerns about the possibility that a member of the University community may have carried out or has begun to carry out research involving human participants that has not received REB approval.
- 1.9 The REB does not have the power to place or cause to be placed in any member of the University research community's personnel file, any information related to their research proposals.
- 1.10 It is the responsibility of researchers to determine whether any proposed research project falls under the terms of the Tri-Council policy statement and to submit a proposal for research to the REB.
- 1.11.1 Approval from the REB must normally be received before the data collection phase of the research commences.
- 1.11.2 An exception to this principle can only be made when the researcher has written permission signed by the Chair of the Research Ethics Board.

2.0 **REB Membership**

- 2.1.1 The membership of the REB shall consist of 6 members (including men and women) as follows:
 - o one faculty member to serve as Chair;
 - at least two faculty members, who have broad expertise in the methods or in the areas of research covered by the REB;
 - o at least one faculty member who is knowledgeable in ethics;
 - at least one faculty member who is knowledgeable in the relevant law;
 and
 - one member from the community served by St. Francis Xavier University, who has no formal affiliation with the institution.
- 2.1.2 For the ethical review of biomedical research or other research of a highly technical nature, an additional member who is knowledgeable in the relevant discipline or in the law related to it may be added on an *ad hoc* basis.
- 2.1.3 If legal expertise should be required with respect to the review of a specific application, the designated person will be someone other than the University's own legal counsel.
- 2.2 Committee members shall normally serve three year terms.
- 2.3 Any member's term may normally be renewed only once.
- 2.4.1 The Chair of the REB will be appointed by the President of St. Francis Xavier University or by his or her designate.
- 2.4.2 The Chair of the REB will normally be a StFX University faculty member who preferably has had previous experience on the REB.
- 2.5 Other members of the REB shall be appointed by the Academic Vice-President and Provost, in consultation with the Chair of the REB, on the basis of experience with, or interest in, the ethics of human research and in accordance with Tri-Council policy.

3.0 Research Ethics Board Procedures

- 3.1 The REB shall require a quorum of four people at all meetings concerned with the ethical approval of research proposals [but see clause 4.0 dealing with Expedited Review].
- 3.2.1 In accordance with the Tri-Council policy statement, the REB shall ensure that its procedures are consistent with standards of natural justice.
- 3.2.2 The REB shall also ensure that its decisions are fair, impartial, and equitable.
- 3.3 The REB shall keep and maintain minutes of all meetings and records of all decisions, including requests for clarification, or modification of submitted research proposals.
- 3.4.1 The REB will approve or reject research proposals only on the basis of their compliance with Tri-Council policy.
- 3.4.2 The REB may propose changes to proposals in order that they comply with Tri-Council policy.
- 3.4.3 The REB may also take action to terminate any proposed or ongoing research involving human participants that, in its view, violates Tri-Council policy.
- 3.5 The REB shall meet regularly at announced times and will consider all major matters, including the regular review of research proposals involving humans, in face-to-face meetings as outlined by the Tri-Council policy statement [but see clause 4.0 dealing with Expedited Review].

- 3.6.1 The review of research carried out by undergraduate students as part of their course work, as an independent study, and including honours theses shall be delegated to the departmental, school, or programme level [see 1.4.1-1.4.4 above].
- 3.6.2 The University REB shall periodically review departmental, school, or programme ethics review procedures to ensure compliance with the Tri-Council policy statement.
- 3.7 The Research Ethics Board shall report to Senate through the Academic Planning and Priorities Committee.
- 3.8 The Research Ethics Board shall make recommendations to the Tri-Council with regard to its policies.

4.0 **Expedited Review**

- 4.1 Researchers can request an expedited review by submitting a fully completed research proposal and the required forms to the REB Chair.
- 4.2 An expedited review does not require a face-to-face meeting of the full REB. The Chair, however, may reject any application for an expedited review and present the case to the full REB at its next regular meeting.
- 4.3.1 The REB review process will only be expedited in cases where the research clearly involves no more than minimal risk, as defined by the Tri-Council policy statement.
- 4.3.2 It is the responsibility of the researcher to document and make the case for there being only a minimal risk to research participants, as part of the application for an expedited review.
- 4.4 An expedited review can also be requested and will normally be granted in the case of a review of on-going research, which has: previously been approved by the REB; where the applicant has an up-to-date file with the REB; and, where there has been no significant changes to the originally approved research processes and aims.
- 4.5 When an expedited review is in order, it will be normally be undertaken by the REB Chair (or designate) and one other member of the REB.
- 4.6 An expedited review will normally be completed in less than two weeks from the date of submission.
- 4.7 The Chair will report any requests for expedited reviews and the results of such reviews to the full REB at its next regular meeting.

5.0 Appeal Procedures

5.1 A Letter of Agreement has been signed between St. Francis Xavier University and the University of Prince Edward Island which outlines the procedures whereby the REB of each University will serve as the appeal board for the other.

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