



## AC.4.4.1 Research Requiring Ethics Review

### Schedule A: SAIT Research Ethics Board

#### A. Authority

SAIT's Research Ethics Board ("REB") shall review research pursuant to policy AC.4.4 Human Research and its accompanying procedure. Researchers shall submit their proposals for ethics review to the REB established by SAIT, subject to the provisions of Schedule B.

#### B. Terms of Reference

1. The REB approves, rejects, proposes modifications to or terminates any proposed or ongoing research which is subject to REB review in order to protect human research participants. A decision of the REB to allow research on ethical grounds is final. A decision of the REB to disallow research on ethical grounds, unless reversed by the REB on reconsideration pursuant to the procedure, may be reversed only through the appeal process.
2. The REB shall suspend any ongoing research under its purview that it deems to pose an unacceptable risk of harm to participants.
3. The REB shall advise on developing processes for implementing the procedures.
4. In order to fulfill its primary duties of conducting objective reviews, the REB shall have independence in its decision-making.
5. The REB shall have appropriate financial support and autonomy to carry out its duties.

#### C. Membership

1. The REB shall consist of at least five members, one of whom shall be the chair, including both men and women, and comprising at least:
  - a) Two members from within the Academic Division who have a broad knowledge and expertise of relevant research disciplines such as technology, science or engineering;
  - b) One member knowledgeable in ethics;



- c) One member knowledgeable in relevant law; and
  - d) One member who has no formal affiliation with SAIT, and who shall be recruited from the community served by SAIT: this member may not be the chair.
2. At the discretion of the REB chair, additional substitute members may be appointed on an ad hoc basis, or outside advice and opinions solicited, when special expertise regarding participant populations, research disciplines, methodologies or other matters is required to reach a competent decision.
  3. All REB members shall be competent in completing an independent research ethics review (judging the ethical acceptability of proposals) and shall be knowledgeable about specific procedures of the REB of which they are members.
  4. The members and chair of the REB will be appointed by the president and CEO for a three year term which may be renewed, with terms overlapping to ensure diversity of opinion and to maintain continuity.

#### **D. REB Assessment, Decision-Making and Processes**

1. Proportionate Approach to Ethics Assessment
  - a) SAIT uses a proportionate approach to ethics assessment for both proposed and ongoing research as recommended in the TCPS2. The more potentially harmful and invasive the research is to participants, the greater shall be the ethical scrutiny to which the research is subjected.
  - b) Except as permitted here, any ethics review required by the procedure shall be a full REB assessment at a meeting. The REB will establish an expedited review process by the REB chair or a member or members of the REB designated by the chair where the research subject to the review is deemed to pose no more than minimal risk as defined in the TCPS2, p.23. Schools may adopt processes for students to conduct research as part of their course work which can be reviewed by specially constituted school boards, provided the research poses no more than minimal risk.
  - c) All levels of review will be reported through the REB.

## 2. Ethics Proposals

- a) The REB shall render a decision no more than 45 calendar days from the receipt of a properly completed application. Frequency of meetings should reasonably reflect the needs of the institution.
- b) Research projects are a significant source of proposals for human ethics review. Proposals may be for classroom or laboratory demonstration of human research procedures or result from the assignment to students of research projects that are conducted outside the classroom. Because the underlying principle is that of protection of human participants, all such procedures must be reviewed. In order to assist researchers, the REB will establish and advertise special processes for researchers.
- c) Ethics review pursuant to the procedure shall be based upon fully detailed research proposals. Researchers shall submit their proposals for ethics assessment in the format prescribed by the REB to either the REB chair or such person designated by the chair to assess the level of review that is required. The chair or designate shall determine whether the proposal poses greater than minimal risk and therefore must receive full REB review at a meeting of the REB or poses no more than minimal risk and therefore may receive expedited review.
- d) The work of the REB should be unconstrained by the implications of its decisions for research funding. For this reason, ethics review of research funding proposals normally shall be reviewed prior to submission of proposals to the funding agencies, even if the funding agency accepts post-submission ethics review results. If a full review cannot be completed prior to funding application submission, however, the REB chair is authorized to conduct a preliminary review and when appropriate issue a provisional ethics approval for the project. Final approval shall be contingent on complete review of the proposal at a meeting of the REB, or where permitted and appropriate, through the REB's expedited review process.

## 3. Release of Funds

- a) Funding organizations sometimes require or accept proposals written at a general level of description (for example, the proposals are not fully detailed). Researchers subsequently must submit fully detailed proposals to the REB for review prior to commencement of the research.
- b) It is the responsibility of the researcher to ensure that all specific requests for information or conditions related to ethics review imposed on a grant are satisfactorily addressed before the funds are released by the institution.

- c) Ethics review issues or conditions will be communicated to the chair of the REB. SAIT's Finance department will only release funds when the director, Applied Research and Innovation Services, confirms and approves that all requests for information and conditions for ARIS-related research have been satisfactorily met.

#### 4. Scholarly Review

- a) REB members shall satisfy themselves that the research design and methods of projects that pose more than minimal risk are capable of addressing the questions being asked in the research.
- b) REB members shall base their judgment about scholarly value on a global assessment of the degree to which the research might further the understanding of a problem, issue or phenomenon; it shall not be based on methodological biases or a preference for particular procedures or on the judgment that another approach is possible. The REB shall recognize that theoretical or methodological preferences are often open to debate and take this into account to ensure fair judgment.
- c) There is no such thing as a definitive study; the significance of any individual study, even when viewed in retrospect, is not always immediately apparent and can be trivialized. Accordingly, the benefit of a particular research project should often be judged within the context of a research program, taking into account the expertise and experience of the faculty. An integral part of some research programs is the pilot study, the results of which may be only suggestive but which can provide important indications of how to proceed with the research. The value of pilot studies is often indirect and may be better evaluated in the broader context of a research program; otherwise, pilot studies are evaluated under the normal ethical guidelines.
- d) Research in the humanities and social sciences which poses, at most, minimal risks shall not normally be required by the REB to be peer reviewed in order to determine capacity to address the questions being asked.
- e) Certain types of research, often from social science and humanities disciplines, may legitimately have negative effects on public figures or on organizations. Such research should not be disallowed automatically because of a negative imbalance of benefits and harms. The safeguard for those in the public arena is through public debate and discourse and through action in the courts.

## 5. Decision-Making Standards and Review Procedures

- a) The Protection of Human Research Participant Procedure forms the basis of decision-making by the REB. The REB shall be familiar with the commentary contained in the TCPS2 and shall refer, where appropriate, to other external policies and commentaries.
- b) REB meetings at which full reviews of proposals are conducted shall be face-to-face. Quorum for REB meetings shall be, at the minimum, three permanent REB members.
- c) The REB shall accommodate reasonable requests from potential researchers to participate in discussions of their proposals, but the potential researchers cannot be present when the REB makes their decisions.
- d) The REB shall develop procedures to ensure the impartiality and fairness of both its full and expedited review processes and to avoid conflicts of interest. Members shall not be present during REB discussions of research with which they are associated, whether the proposal is from a student, faculty member, or external researcher. Similarly, members shall not be involved in the expedited review of research with which they are associated.
- e) Decisions of the REB shall be reached by consensus wherever possible. If the REB cannot achieve consensus, however, the decision shall be based on majority vote. For expedited reviews, the decision to approve must be made by consensus if two or more REB members conduct the review. Lack of consensus in such cases shall automatically result in referral of the proposal for full REB assessment unless the applicant chooses to withdraw the proposal.
- f) When the REB identifies factors that may jeopardize the well-being of human participants, such issues should be resolved cooperatively by the REB and the researcher. When a REB considers a negative decision, it shall provide the researcher with all reasons for doing so and give the researcher an opportunity to reply before making a decision.
- g) When the REB denies an application or makes approval contingent on changes to the proposal, the researcher has a right to request, and the REB has an obligation to provide, reconsideration based on the researcher's rebuttal to the concerns identified by the REB.
- h) When the REB denies an application or makes approval contingent on changes to the proposal, it shall provide the researcher with written grounds for the decision.

- i) Schools may adopt procedures by which research conducted by students as part of their course work can be reviewed by specially constituted school boards, linked to the REB, as a special form of expedited review (see Schedule B, an Associated Document to this procedure).

## 6. Record Keeping and Proposals

- a) The REB shall prepare and maintain minutes of all its meetings. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of the institution, researchers and funding agencies.
- b) The REB shall maintain one copy of each research proposal it considers, either during face-to-face meetings or through expedited review, as part of its records.
- c) The REB may establish additional requirements for record-keeping relevant to the disciplines they represent, to granting agency requirements and to legislative requirements (for example, the province of Alberta's *Freedom of Information and Protection of Privacy Act*). The minimum amount of time that REB records shall be kept is three years beyond the completion of the specific approved project.

## 7. Reports of Unanticipated Issues

- a) Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare.
- b) Any unanticipated issue that increases the level of risk to participants or has other ethical implications should be reported to the REB without delay. Minor deviations from the research (for example, a slight increase or decrease of testing time, a wording adjustment on a question) should not require immediate reporting to the REB. The report to the REB should include a description of the unanticipated issue or incident, including details of how the researcher(s) dealt with the situation.

## 8. Reports

- a) Certificates of Ethics Approval, signed by the chair of the REB, will be issued to the principal investigator(s).

- b) Periodic activity reports from the REB including reviews done by School Review Committees will be made to the vice president, academic.

#### 9. Continuing Research Ethics Review

- a) The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects) and an end-of-study report (projects lasting less than one year).
- b) Research that involves minimal or no risk to participants should be held to the minimum requirements for continuing ethics review, that is, an annual report. Consistent with a proportionate approach, the REB has the option of requesting more frequent and/or more substantive reports if necessary.
- c) SAIT has a responsibility to provide necessary resources to the REB to assist it in fulfilling its continuing ethics review responsibilities. Continuing research ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical standards.
- d) The REB makes the final decision about the nature and frequency of continuing ethics review.
- e) Researchers' responsibilities include monitoring their research to ensure that it is conducted in an ethical manner, reporting unanticipated issues or changes to the research, supervising all team members in the application of the research procedures and ensuring that they are properly qualified and versed in the conduct of ethical research.

#### 10. Appeals of REB Decisions

- a) Researchers have the right to request, and the REB has an obligation to provide, prompt reconsideration of decisions affecting a research project. Researchers and the REB should make every effort to resolve disagreements they may have through deliberation, consultation or advice. If a disagreement between the researcher and the REB cannot be resolved through reconsideration, the researcher has the option of appealing the REB decisions through the established appeal mechanism.
- b) The REB's appeal mechanism is the University of Calgary's Research Ethics Appeal Board (REAB) as agreed to in a co-signed contract on file in the office of Applied Research and Innovation Services.

- c) A request for appeal must be the last resort and may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS2. The Appeal Board's decision is binding.

#### **E. Review of Off-Campus Research**

SAIT's jurisdiction to prohibit one of its members from conducting research which is subject to the ethics review process contained in this procedure is not diminished by the fact that the research project shall be conducted off-campus, whether in Alberta, in Canada or elsewhere. Such research shall be subject to prospective ethics review both by the researcher's (SAIT's) REB, and by the applicable ethics board or process, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards where the research is to be conducted.

#### **F. Review of Multi-Centered Research**

1. In the proposal for ethics review, a researcher must identify if the work being done involves multi-centered research. To facilitate the coordination of ethics review, when submitting a proposal, the researcher may wish to distinguish between core elements of the 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.
2. Where research involves two or more REBs, SAIT's REB will coordinate its review of multi-centered projects, communicate any concerns it may have with other REBs reviewing the same project, and coordinate with other REBs in a timely and effective manner regarding the respective approval processes.