



SUBJECT: Ethics of Research Involving Human Subjects	CATEGORY: Governance – High Risk Decisions	NO. G-4.4
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PREAMBLE

Norms for the ethics of research involving human subjects are developed and refined with an ever-evolving societal context, elements of which include the need for research within the research community, moral imperatives and ethical principles, and the law. There is a professional responsibility of researchers to adhere to ethical norms and codes of conduct appropriate to their respective disciplines.

All research at SIAST must demonstrate that appropriate methods will be used to protect the rights and interests of the subjects in the conduct of research. It is of the utmost importance to SIAST that safety, health and welfare are provided and that no human rights are violated when research that involves human subjects is being conducted at SIAST or under the aegis of SIAST. At SIAST, the purpose of ethics review of research involving human subjects is the protection of research subjects; the protection of SIAST, including employees and students; and the education of those involved in the research. SIAST will ensure that research conducted on human subjects meets requirements of major granting agencies and regulatory bodies and that appropriate safeguards are provided for those involved in the research.

POLICY

All research involving human subjects undertaken by members of, or conducted at, SIAST including all SIAST board members, management, faculty, staff, trainees, associates, affiliates, and students (including students carrying out research as part of class assignments) shall fall under the jurisdiction of the SIAST Research Ethics Board (SIAST REB), irrespective of the source of funding (if any) and irrespective of the location of the project so long as the researcher represents the work as SIAST research. Projects conducted by researchers outside the SIAST community who access SIAST resources (either equipment or personnel) will also fall within the jurisdiction of the SIAST REB. Specifically, all research conducted under the auspices of SIAST is subject to this policy. This includes research funded by SIAST or by other agencies, conducted on or off a SIAST campus, in Canada or outside Canada, whether the human

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subjects are from SIAST or not, whether the subjects are paid or not, or whether the research is published or not.

The SIAST REB and all researchers, including affiliates, shall adhere to the Tri-Council (Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada, Social Sciences and Humanities Research Council of Canada) principles set out in the “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans” (TCPS). The SIAST REB shall have the mandate to approve, reject, propose modifications to, and terminate any proposed or ongoing research involving human subjects conducted at SIAST or under the aegis of SIAST using the consideration in the TCPS.

DEFINITIONS

Research is a systematic investigation with the intent to facilitate a deeper and broader understanding of a phenomenon or experience, or to establish facts, principles and generalizable knowledge.

Human research refers to research that will involve a collection of human specimen, data or information from persons, through intervention or otherwise. This human research may include, but is not limited to, procedures of low degree of invasiveness such as surveys, interviews, naturalistic observations, exercise or psychometric testing, examination of patient records, as well as more invasive procedures such as blood sampling or administration of substance.

A **human subject** is a person or an individual who, by virtue of his/her involvement in a data gathering situation or activity, is a primary source of data or information.

A **research ethics protocol** is a document submitted by an applicant (e.g. a SIAST employee) for consideration by the Research Ethics Board. This document contains a detailed description of the rationale to conduct human research and the purpose of the study, including the procedures to be followed during the study and managing the results.

Minimal risk means the risk of harm anticipated in the proposed research is not greater or more likely than the risk normally encountered in life.

PROCEDURES

The SIAST REB and all researchers, including affiliates, shall follow the principles set out in the “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans” (TCPS). All research that involves living human subjects requires review and approval by the SIAST REB in accordance with the TCPS Policy Statement before the research is started, except as stipulated below.

1. Research Subject to the SIAST REB Review and Approval

All research at SIAST or under the aegis of SIAST involving human subjects needs prior SIAST

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REB review and approval and applies to the following:

- 1.1. All types of research conducted with human subjects when research data are derived from, but not exclusively limited to
 - information collected through intervention or interaction with living individual(s).
 - identifiable private information about individuals.
 - information collected through naturalistic observation of humans, except as stipulated in Section 2.
 - human organs, remains, tissues or body fluids, cadavers, embryos or fetuses.
 - written or recorded information derived from individually identifiable human subjects.

- 1.2. In addition, ethics review is required for the following categories of research that may be overlooked
 - pilot studies and feasibility studies, even those involving only one human subject.
 - projects that involve the secondary use of data on human subjects gathered in earlier projects.
 - research conducted by administrative and academic units that involves the collection of survey replies or the use of records as it correlates to survey replies from human subjects (e.g. students, staff and/or faculty members).
 - all independent student projects conducted in partial fulfillment of certificate, diploma or degree requirements. Research projects conducted as part of formal course requirements may, in certain circumstances, require the SIAST REB review and approval. It is incumbent upon the SIAST course instructor to check the applicability of this requirement with the SIAST REB chair.
 - Research involving naturalistic observations requires an REB review and approval with some exceptions (see 2.3)

2. Research Not Subject to the SIAST REB Review

Prior review and approval from the SIAST REB will not be required for the following types of research:

- 2.1. A limited type of research most often found within the humanities, fine arts, and in some historical research which involves
 - (a) a public database where aggregated data that cannot be associated with any individual are obtained.
 - (b) information already in public domain (i.e. autobiographies, biographies, or public archives).

- 2.2. Archival analysis of records by SIAST departments normally engaged in the collection, maintenance and analysis of such records.

- 2.3. Naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings where the participants are seeking public visibility.

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- 2.4. Class research projects which involve human subjects and which are conducted by students on other members of the class as exercise to learn how to conduct research.
- 2.5. Evaluations of courses or training programs that are designed to provide feedback.
- 2.6. Preliminary and informal interviews or casual conversations that are carried out to help clarify the design of a research project.
- 2.7. Information gathering procedures in support of the general administration of SIAST where the preliminary purposes are
 - to diagnose problems, identify appropriate solutions, provide advice for operation management, or assess performance.
 - to collect data primarily designed to affect the operations of SIAST through affirming satisfaction with the status quo or leading to quality improvement.
- 2.8. Information gathering procedures to collect institutional level data for administrative purposes.
- 2.9. Research undertaken as a teaching exercise and entailing minimal risk shall be reviewed by the program head or designate, and if he/she deems it appropriate he/she will forward it to the SIAST REB. In general, interviews, surveys or naturalistic observations where no personal or private confidential information is used or disclosed will not require REB approval.

3. In the Case of Doubt

For research/scholarly work where the researcher is in doubt whether the SIAST REB review and approval is required, it is the responsibility of the researcher to obtain a written opinion of the chair of the SIAST REB as to whether or not the research must be subjected to prior ethics review and approval.

4. Academic Freedom

SIAST and all persons involved in the ethics review process shall act in such a manner as to ensure that there is not infringement of the academic freedom of researchers. However, SIAST and its researchers also recognize that with freedom comes responsibility, including the responsibility to ensure that research involving human subjects meets high scientific and ethical standards.

5. Compliance

SIAST requires all faculty members, staff and students, as well as external researchers conducting research at SIAST, or under the aegis of SIAST, to adhere to this policy and to the procedures that are derived from it. SIAST considers the improper treatment of human subjects in research to be a serious offence, subject to severe penalties, including, but not limited to, the withdrawal of privileges to conduct research involving human subjects or disciplinary action.

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6. Responsibilities of Researchers

Whenever research involving human subjects is to be performed at SIAST or under the auspices of SIAST or by any SIAST researcher, the researcher is responsible for meeting the following requirements:

- 6.1. Reading and becoming thoroughly familiar with applicable SIAST ethical guidelines.
- 6.2. Ensuring that the research being conducted is scientifically valid and/or appropriate in a scholarly sense and that the benefits to knowledge that will result from the research warrant the investment of time, effort and risks to be incurred by the number of human subjects for which the research is planned. Scientifically invalid research, research that is more intrusive or requires more subjects involved in the research procedures than those warranted by the research design is unethical. The researcher shall carefully monitor and assure the validity of the research submitted to the SIAST REB.
- 6.3. Determining if the proposed research requires ethics review. If there is any uncertainty about whether the research requires ethics review and approval, the researcher shall consult the chair of the SIAST REB for advice and decision.
- 6.4. Notifying the SIAST REB of the proposed research by submitting a completed Human Subject Research Ethics Protocol¹, accompanied by any supplementary materials necessary for full ethics review, and providing any additional information requested by the SIAST REB in a timely fashion.
- 6.5. Not involving human subjects in the proposed research until the SIAST REB has informed the researcher of approval in writing for the use of human subjects in the research.
- 6.6. Abiding by all decisions of the SIAST REB, including following all modifications required for the SIAST REB approval and not undertaking the research if it has not been approved.
- 6.7. Obtaining free and informed consent from all subjects involved in research.
- 6.8. Maintaining the confidentiality of data obtained from subjects in the manner required by the SIAST REB and relevant organizations.
- 6.9. Promptly reporting to the chair of the SIAST REB any injuries to human subjects, any unanticipated problems which involve risks or unusual costs to the subjects, or other adverse events resulting from the research. Initial reports may be verbal; subsequent reports shall be in the manner required by the SIAST REB, in most cases in writing.
- 6.10. Promptly reporting to the chair of the SIAST REB any proposed changes in the

¹ A copy of the Human Subject Research Ethics Protocol is available from the POP manual or secretary to the REB.

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research which would result in a significantly different involvement of human subjects and obtaining the approval of the SIAST REB prior to the changes being made, except where necessary to eliminate apparent and immediate hazards to subjects.

6.11. Promptly reporting to the chair of the SIAST REB any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans, for subject involvement and obtaining the approval of the REB prior to the involvement of any subjects.

6.12. Promptly reporting to the chair of the SIAST REB any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by the SIAST REB by any individual associated with the research.

7. Free and Informed Consent of Subjects

7.1. The researcher is responsible for obtaining free and informed consent from all prospective subjects, or authorized third parties, prior to commencing research activities. Free and informed consent must be maintained throughout participation in the research. Free and informed consent must be given voluntarily, without manipulation, undue influence or coercion.

7.2. Evidence of free and informed consent in the form of a signed document by the subject or authorized third party must be obtained in writing and stored in a secure repository. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedure used to seek free and informed consent must be documented.

7.3. The SIAST REB may approve a consent procedure if the SIAST REB finds that

- the research involves no more than minimal risk to the subjects.
- the alteration or waiver of the consent procedure is unlikely to adversely affect the rights and welfare of the subjects.
- the research could not practicably be carried out without the alteration or waiver of the consent procedure.
- whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation.
- the alteration or waiver of consent does not involve a therapeutic intervention.

7.4. Participants in naturalistic observation studies normally do not give informed consent because they are unaware they are being observed. The SIAST REB can approve such projects as long as the research records protect the identities of the subjects, as well as their dignity. If the research environment is staged, however, special care must be taken to ensure the privacy, well being, safety, and dignity of the subjects.

7.5. Researchers shall provide prospective subjects or authorized third parties with

- information that the individual is being invited to participate in a research project.

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- a statement of the research purpose, identity of the researcher, the expected duration and nature of participation and a description of the research procedures.
- a description of the reasonably foreseeable harms and benefits that may arise from research participation as well as the likely consequences of non-action, particularly in research related treatment.
- an assurance that prospective subjects are free not to participate and have the right to withdraw at any time without prejudice to pre-existing entitlements.
- the possibility of commercialization of the research findings, and the presence of any apparent, actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

7.6. In research that involves randomization and blinding in clinical trials, neither the research subject nor those responsible for their care know which treatment the subjects are receiving before the project commences. This type of research should not be considered as a waiver or alteration of the requirements to obtain a free and informed consent and the SIAST researcher must obtain a free and informed consent from the research subjects before this type of research commences.

8. Research on Subjects Who are not Legally Competent

8.1. Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when

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

8.2. For research involving legally incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- The researcher shall show how the free and informed consent will be sought from the authorized 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 of a legally incompetent subject in research, so long as the subject remains incompetent.
- When a subject who was entered into a research project through third-party authorization becomes competent during the project, his/her informed consent shall be sought as a condition of continuing participation.

8.3. When 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/her participation.

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9. Research in Emergency Health Situations

9.1. Research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of the research by the SIAST REB. The SIAST REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his/her authorized third party if ALL of the following apply:

- A serious threat to the prospective subject requires immediate intervention.
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care.
- Either the risk of harm is not greater than that involved in standard efficacious care, or it is not clearly justified by the direct benefits to the subject.
- The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research.
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so.
- No relevant prior directive by the subject is known to exist.

9.2. When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

10. SIAST Ethics Board

10.1. Composition of the SIAST Research Ethics Board

SIAST will have one Research Ethics Board and all submissions for ethics review and approval will be sent to that Board. The SIAST Research Ethics Board will have five members. The SIAST REB shall have the mandate to approve, reject, propose modifications to, and terminate any proposed or ongoing research involving human subjects conducted at SIAST or under the aegis of SIAST using the consideration in the TCPS. The Board shall consist of both men and women:

- At least two members have broad expertise in the methods or in the areas of research that are covered by the REB.
- At least one member is knowledgeable in ethics.
- For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research.
- At least one member who has no affiliation with the institution, but is recruited from the community served by the institution.

The members and the chair of the SIAST REB will be appointed by the SIAST President and CEO on the recommendation by the Associate Vice-President, Educational Services, in

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accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Human Subjects. The members shall be knowledgeable of the TCPS.

10.2. Tenure on the SIAST REB

The normal tenure on the SIAST REB will be three years, but will not exceed six years. No more than one-third of the board will be replaced each year. A member serving for six years may be re-appointed to the Board after a year of absence from the Board. Regular attendance by REB members at meetings is important and frequent unexplained absences will be construed as a notice of resignation. The Associate Vice-President, Educational Services, in consultation with the chair or Director, Applied Research, may appoint substitute members to serve as replacement for the members when they are not able to attend.

10.3. Quorum

The Board will strive for consensus in its decision making, but if not possible the decision will be based on majority vote of the appointed members. A quorum will consist of more than 50% of the voting members provided the members in the audience possess the expertise and background as stated in 10.1.

10.4. Ad Hoc Members

From time to time SIAST REB will call on specialists to provide expert advice. In each case, the responsibility of appointing these ad hoc members will rest with the chair. Such ad hoc members will not be voting members, but may participate in the SIAST REB deliberations.

10.5. Meetings

The SIAST REB members will meet regularly at dates and times announced in advance. Normally they will meet on a bi-monthly basis (one meeting every two months), but meetings may be cancelled if no requests for review and approval are received before the submission deadlines.

10.6. Records

Minutes of all SIAST REB meetings shall be prepared and maintained by the SIAST REB. The minutes shall clearly document the SIAST 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. The minutes will be stored in the Office of Applied Research and Innovation.

11. Procedural Guidelines for the Review of Research Proposals

A SIAST REB approval must be obtained before the work begins. Submissions for review by the

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SIAST REB must be sent to the SIAST REB chair using appropriate forms and according to the instructions on the forms. Forms are available from the Office of Applied Research and Innovation. Prospective applicants are encouraged to contact the secretary to the SIAST REB, SIAST REB chair or any members of SIAST REB for assistance in selecting the appropriate forms.

12. Research Proposal Review Process

12.1. Scholarly Review

12.1.1. In the case of research proposals that present more than minimal risk, the design of the project must be peer reviewed to ensure that it is capable of addressing the question(s) being asked in the research. Sufficient peer review may be considered to be any one of the following:

- Successful approval by the SIAST REB (if the research is in the field of the SIAST REB expertise).
- Successful funding of the grant proposal by a funding agency.
- Ad hoc independent external review reporting directly to SIAST REB.

12.1.2. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

12.1.3. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the SIAST REB to be peer reviewed.

12.1.4. 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 must 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.

12.2. Principle of Proportionate Review

The SIAST REB will take a proportionate approach based on the general principle that the more invasive the procedures in the research, the more diligent the assessment of the perceived risk inherent in the study procedures must be.

12.3. Normal Review Process

12.3.1. The SIAST REB members shall meet face-to-face in order to review submitted proposals. In the case of a controversial proposal, the SIAST REB may invite the researcher for a face-to-face meeting in order to consider the ethical solution proposed by the researcher and to discuss problems arising from his/her study.

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- 12.3.2. The SIAST REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but they may not be present when the SIAST REB is making its decision.
- 12.3.3. Minutes will be kept for these meetings and inserted into the appropriate case files. The minutes of the meetings will document the decisions and dissents of the SIAST REB and the reason for them.
- 12.3.4. The SIAST REB shall keep an “open file” in a secure location determined by the chair of the REB, for researchers applying for ethical approval. The file shall be opened by the chair when sufficient information has been submitted by the researcher to start the review process. The original application, description of research and methodology, correspondence, relevant documents, ethical certificates, revised materials and any comments from the public or other information relevant to the research project shall be kept in the file.
- 12.3.5. It is the responsibility of the researcher to address all the recommendations made by the SIAST REB and keep the file complete and up-to-date at all times. When the research project is finished and the researcher notifies the SIAST REB, these files shall be “closed” and kept for a period of at least five (5) years by the SIAST REB as records demonstrating compliance with the TCPS. The files will remain the property of SIAST and cannot be removed by the researcher. These files shall be subject to audit by authorized representatives of SIAST, members of appeal committee and funding agencies. The SIAST REB file on application for ethical review should contain the following documents:

- Application Form
- Trial Protocol and Amendments
- Written informed consent and any updates
- Subject Recruitment procedures (i.e. advertisements)
- Investigator’s brochure
- Available safety information
- Information about payments and compensation available to subjects
- Investigator’s current CV and other documents of qualifications
- Any other documents that REB would need to fulfill its responsibilities

All research receiving an ethical approval, whether through a normal or expedited process, as well as those receiving program head (or designate) review, shall require a proper file showing compliance with the TCPS. Insufficient information in the file is grounds for refusing or delaying ethical approval.

12.4. Expedited Review

Expedited review does not require face-to-face meetings of the SIAST REB members. The researcher must choose to apply for expedited or full review and the SIAST REB chair may reject any application for expedited review and refer it to the SIAST REB for full review. The chair must report requests for expedited review and results of such reviews to the full SIAST REB in a timely manner (i.e. as soon as reasonably possible). Expedited review is review

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by two members (the chair may be one of them) rather than the full SIAST REB. It is available only in cases that fulfill the following criteria:

12.4.1. Research which involves no more than minimal risk (as defined in the TCPS: “If potential subject can reasonably be expected to regard the possibility and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject on those aspects of his/her everyday life that relate to research, then the research can be regarded as within the range of minimal risk.”) Given the heterogeneous nature of subjects, a “reasonable person’s” definition of minimal risk as is often employed in the courts concerning subjective harms will also be acceptable to the SIAST REB. The researcher is responsible for an acknowledgement of minimal risk to the SIAST REB.

12.4.2. Research projects which have already received approval by the SIAST REB, have complied fully with any requirements, have an up-to-date file, and the applicant is simply renewing the ethical approval without significant changes to the ongoing research process.

12.5. Departmental Review

This policy requires that all research involving human subjects must be submitted to the SIAST REB. If, however, a study is a teaching exercise (i.e. part of diploma or certificate or degree) and entailing no more than minimal risk, it must be reviewed by the SIAST program head or designate on behalf of the SIAST REB, and in compliance with the TCPS. The program head or designate must report results of such reviews to the SIAST REB in a timely manner (i.e. as soon as reasonably possible).

Student research deemed to be beyond minimal risk must be reviewed by the SIAST REB.

The program head (or designate) review must not be used to review research undertaken by a student as part of a SIAST faculty member's research program.

12.6. Review of Multi-Centered Research

It is the responsibility of the researcher to ensure that multi-centered research is reviewed by all institutions where the research is to be undertaken. The SIAST REB may share documents and findings with REBs of other institutions. The SIAST REB may also review the documents and findings of REBs of other institutions as part of the ethics review process.

If research is undertaken as part of a university program where the university REB approval is required, SIAST must provide a preliminary authorization for access to the site. This approval for access will be conditional upon SIAST receiving a positive review and approval from the university REB and an agreement from the SIAST REB chair.

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12.7. Review of Research in Other Jurisdictions or Countries

Research performed in another jurisdiction or country shall undergo ethics review by the SIAST REB and, where such exists, the equivalent REB in the country and jurisdiction where the research is conducted.

12.8. Continuing Ethics Review

The SIAST REB's approval of a research project covers only the procedures outlined by the applicant in his/her original application. Any changes in the procedures affecting interaction with human subjects must be reported to the SIAST REB. Significant changes will require the submission of a revised application for ethics approval.

12.8.1. Ongoing research shall be subject to continuing ethics review. The chair of the SIAST 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 SIAST REB. Problems or complaints will be taken seriously by the SIAST REB, and researchers may be asked to modify their studies in view of such complaints.

12.8.2. All protocol approvals are for a maximum of one (1) year, and may be renewed by submission of an annual report prior to the anniversary date of the original protocol approval. Such reports must clearly indicate the status of data collection and, if there will be changes to the protocol that was approved, specify in detail the nature of any changes that are required. If no substantial change has been made to the research plan or research protocol, the chair of the SIAST REB may issue a one-year extension. If, in the opinion of the SIAST REB chair, the research plan or research protocol has been substantially changed, re-submission and review by the SIAST REB is required. Protocol submissions for data collection for a period less than one year lapse at the end of the time specified.

12.8.3. The researcher shall promptly notify the SIAST REB when the project concludes.

12.9. Conflict of Interest

If the SIAST REB is reviewing research in which a member of the SIAST REB has a personal interest in the research under review (e. g. as a researcher or as an entrepreneur), conflict of interest principles require that the member declare his/her interest and remain neutral or not be present while the SIAST REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the SIAST REB member in potential conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the SIAST REB will make a final decision regarding the conflict and how to proceed.

13. Decisions of the SIAST REB

After review by the SIAST REB, the protocol submission may be:

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- approved as submitted
- approved with suggestions for minor changes
- approved with conditions (that must be met before final approval is granted)
- deferred, pending receipt of additional information or major revisions
- not approved

13.1. The SIAST REB shall notify each researcher, in writing, of its decision regarding the proposed research activity. Normally the researcher will accept the proposed modification or offer a counter-proposal to the chair of the SIAST REB. This exchange is concluded normally when an ethically acceptable form for the research is agreed upon. To facilitate the continuing processing of such research ethics protocols between meetings, the SIAST REB must specify conditions that must be met to enable the chair to review and grant approval on behalf of the SIAST REB.

13.2. Researchers have the right to request, and SIAST's REB have an obligation to provide, reconsideration of decisions affecting a research project.

13.3. If the SIAST REB does not approve a research activity for ethical reasons, the notification shall include a statement of the reasons for its decision and the researcher shall be given an opportunity to respond in writing or in person. The chair will make him/herself available to the applicant on a reasonable basis to endeavor to develop a proposal that will meet the ethical standards required by the SIAST REB. The SIAST REB may, at its discretion, review and reconsider its decision to not approve the research activity.

13.4. In the case of ongoing research, the SIAST REB has the authority to terminate research that deviates from an approved research protocol and as a result no longer complies with the criteria set forth in these policies or the TCPS.

Reconsideration

If the SIAST REB decision is negative, the researcher who requested ethics review of his/her proposal has the right to request, and the SIAST REB has an obligation to provide, reconsideration of decisions affecting a research project.

14. Appeal

In cases when researchers and the SIAST REB cannot reach agreement through discussion and reconsideration, the researcher can appeal the REB decision. Researchers must apply in writing to the Senior Vice-President, Academic to appeal the negative SIAST REB decision. Appeals must be in writing, and a copy of the appeal letter must also be sent to the SIAST REB chair. SIAST shall use a duly constituted Appeal Committee to review decisions of the SIAST REB. The appeal committee will be appointed by the senior vice-president, academic and consist of at least five members, none of whom is a member of the SIAST REB. The appeal committee shall have the same constitution as the REB. The appeal committee shall consist of both men and women of whom:

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- At least two members have broad expertise in the methods or in the areas of research that are covered by the SIAST REB.
- At least one member is knowledgeable in ethics.
- For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research.
- At least one member who has no affiliation with the institution, but is recruited from the community served by the institution.

Non-compliance with the substance of the TCPS is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS. The decision of the appeal committee shall be binding.

15. Annual Report Prepared by REB

An annual activity report from the REB will be submitted to the associate vice-president, educational services with a copy to the deans' council.

16. Adverse Events Reports

Normally, it is anticipated that research will proceed with little or no special costs or harm to subjects, beyond those noted in the protocol. However, unanticipated negative reactions by subjects or other unexpected events may occur. Researchers are obliged to immediately report, in writing, any known serious adverse event to the SIAST REB.

17. Administration

SIAST supports the administrative processes and educational activities required by the SIAST REB so that SIAST as a whole remains in compliance with the TCPS.

17.1. Administrative Support

The work involved in the ethical review process must be distributed appropriately among faculty members, staff, researchers, and administrators. SIAST will provide administrative support to the SIAST REB including:

- Distribution of forms and materials necessary for submission of research proposals to the SIAST REB.
- Collection of submissions and distribution of submissions to SIAST REB members.
- Keeping minutes of SIAST REB meetings.
- Storing submissions and related materials in a secure location.
- Supporting the SIAST REB in its educational activities.
- Acting as the point of contact for any of the following agencies NSERC, SSHRC or CIHR.

17.2. Other Duties Related to the Support of the SIAST REB in Carrying Out its Mandate

The SIAST deans and associate vice-presidents will provide significant support to the SIAST REB with respect to:

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- educational activities
- management of the system for reporting research
- ensuring that research projects requiring ethical review are submitted to the SIAST REB.
- advising their faculty members about the need to comply with the TCPS.

Individual departments are expected to support and train faculty and students so that their research projects are ethical and those that exceed minimal risk may be efficiently reviewed by the SIAST REB. Program heads (or designates) must screen student applications for ethical review prior to submission to the SIAST REB where such review is required. The SIAST REB may return applications to the department if they do not conform to the requirements of the TCPS.

17.3. Interpretation

Questions of interpretation or application of this policy or its procedures shall be referred to the associate vice-president, educational services or designate, who will interpret and apply the policy and procedures in congruence with the interpretations of the TCPS and whose decision shall be final.

18. Forms

Ethical guidelines and the required forms for submission to the SIAST REB will be made available from the secretary to the SIAST REB.

Acknowledgement

SIAST would like to thank Red River College (RRC) for the permission to use the RRC's Policies and Procedures related to Research Involving Human Subjects as a template for this policy.

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