SUBJECT:	CATEGORY:	NO.
Ethics of Research Involving Human Participants	**Research and Scholarly Activity**	**1102-G**

PREAMBLE

Norms for the ethics of research involving human participants 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 participants 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 participants is being conducted at SIAST or under the aegis of SIAST. At SIAST, the purpose of ethics review of research involving human participants is the protection of research participants; 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 participants 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 participants undertaken by members of, or conducted at, SIAST including all SIAST, 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 participants are from SIAST or not, whether the participants 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" (TCPS2). The SIAST REB shall have the mandate to approve, reject, propose modifications to, and terminate any proposed or ongoing research involving human participants conducted at SIAST or under the aegis of SIAST using the consideration in the TCPS2.

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 participant** 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" (TCPS2). All research that involves living human participants requires review and approval by the SIAST REB in accordance with the TCPS2 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 participants needs prior SIAST REB review and approval and applies to the following:

1.1. All types of research conducted with human participants 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 participants.

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 participant.
- projects that involve the secondary use of data on human participants 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 participants (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.

2.4. Class research projects which involve human participants 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 participants 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 participants 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 participants or disciplinary action.

6. Responsibilities of Researchers

Whenever research involving human participants 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 participants for which the research is planned. Scientifically invalid research, research that is more intrusive or requires more participants 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 Protocol[1], 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 participants in the proposed research until the SIAST REB has informed the researcher of approval in writing for the use of human participants 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 participants involved in research.

6.8. Maintaining the confidentiality of data obtained from participants 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 participants, any unanticipated problems which involve risks or unusual costs to the participants, 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.

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

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

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.

6.13. Researchers shall provide details to the SIAST REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

6.14. Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

7. Free and Informed Consent of Participants

7.1. The researcher is responsible for obtaining free and informed consent from all prospective participants, 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 participant 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 participants.
- the alteration or waiver of the consent procedure is unlikely to adversely affect the rights and welfare of the participants.
- the research could not practicably be carried out without the alteration or waiver of the consent procedure.
- whenever possible and appropriate, the participants 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 participants, 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 participants.

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

- information that the individual is being invited to participate in a research project.
- 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 reasonable 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 participants 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 participant nor those responsible for their care know which treatment the participants 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 SIAST researcher mush obtain a free and informed consent form the research participants before this type of research commences.

8. Research on Participants 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 participants 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).

8.2. The research does not expose them to more than minimal risks without the potential for direct benefits for them.

8.3. 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 participant'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 participant in research, so long as the participant remains incompetent.

8.4. When a participant 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.

8.5. 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 participant's dissent will preclude his/her participation.

9. Research Involving First Nations, Inuit and Métis Peoples of Canada

Introduction

First Nations, Inuit and Métis communities have unique histories, cultures and traditions. They also share some core values such as reciprocity – the obligation to give something back in return for gifts received – which they advance as the necessary basis for relationships that can benefit both Aboriginal and research communities.

Research involving Aboriginal peoples in Canada has been defined and carried out primarily by non-Aboriginal researchers. The approaches used have not generally reflected Aboriginal world views, and the research has not necessarily benefited Aboriginal peoples or communities. As a result, Aboriginal peoples continue to regard research, particularly research originating outside their communities, with a certain apprehension or mistrust.

The landscape of research involving Aboriginal peoples is rapidly changing. Growing numbers of First Nations, Inuit and Métis scholars are contributing to research as academics and community researchers. Communities are becoming better informed about the risks and benefits of research. Technological developments allowing rapid distribution of information are presenting both opportunities and challenges regarding the governance of information.

This section is designed to serve as a framework for the ethical conduct of research involving Aboriginal peoples. It is offered in the spirit of respect. It is not intended to override or replace ethical guidance offered by Aboriginal peoples themselves. Its purpose is to ensure, to the extent possible, that research involving Aboriginal peoples is premised on respectful relationships. It also encourages collaboration and engagement between researchers and participants.

Building reciprocal, trusting relationships will take time. This section provides guidance, but it will require revision as it is implemented, particularly in light of the ongoing efforts of Aboriginal peoples to preserve and manage their collective knowledge and information generated from their communities.

Interpreting the Ethics Framework in Aboriginal Contexts

There are three principles that express the core ethical value of respect for human dignity – Respect for Persons, Concern for Welfare, and Justice. The three core principles are interpreted as follows:

Respect for Persons is expressed principally through the securing of free, informed and ongoing consent of participants. The concerns of First Nations, Inuit and Métis for their continuity as peoples with distinctive cultures and identities have led to the development of codes of research practice that are in keeping with their world views. Aboriginal codes of research practice go beyond the scope of ethical protections for individual participants, and extend to the interconnection between humans and the natural world, and include obligations to maintain, and pass on to future generations, knowledge received from ancestors as well as innovations devised in the present generation.

Historically, the well-being of individual participants has been the focus of research ethics guidelines. In this Policy, the principle of **Concern for Welfare** is broader, requiring consideration of participants and prospective participants in their physical, social, economic and cultural environments, where applicable, as well as concern for the community to which participants belong. There is an important role of Aboriginal communities play in promoting collective rights, interests and responsibilities that also serve the welfare of individuals.

Aboriginal peoples are particularly concerned that research should enhance their capacity to maintain their cultures, languages and identities as First Nations, Inuit or Métis peoples, and to support their full participation in, and contributions to, Canadian society. The interpretation of Concern for Welfare in First Nations, Inuit and Métis contexts may therefore place strong emphasis on collective welfare as a complement to individual well-being.

Justice may be compromised when a serious imbalance of power prevails between the researcher and participants. Resulting harms are seldom intentional, but nonetheless real for the participants. In the case of Aboriginal peoples, abuses stemming from research have included: misappropriation of sacred songs, stories and artefacts; devaluing of Aboriginal peoples' knowledge as primitive or superstitious; violation of community norms regarding the use of human tissue and remains; failure to share data and resulting benefits; and dissemination of information that has misrepresented or stigmatized entire communities.

Where the social, cultural or linguistic distance between the community and researchers from outside the community is significant, the potential for misunderstanding is likewise significant. Engagement between the community involved and researchers, initiated prior to recruiting participants and maintained over the course of the research, can enhance ethical practice and the quality of research. Taking time to establish a relationship can promote mutual trust and communication, identify mutually beneficial research goals, define appropriate research collaborations or partnerships, and ensure that the conduct of research adheres to the core principles of Respect for Persons, Concern for Welfare – which in this context includes welfare of the collective, as understood by all parties involved – and Justice.

9.1. Requirement of Community Engagement in Aboriginal Research

Where the research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

- research conducted on First Nations, Inuit or Métis lands;
- recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
- research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;
- research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and
- interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

9.2. Respect for First Nations, Inuit and Métis Governing Authorities

Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nations, Inuit or Métis authority, researchers shall seek the engagement of formal leaders of the community, except as provided under Articles 9.5, 9.6 and 9.7.

Research ethics review by the institutional REB and any responsible community body recognized by the First Nations, Inuit or Métis authority (see Articles 9.9 and 9.11) is required in advance of recruiting and seeking and obtaining consent of individuals.

9.3. Nature and Extent of Community Engagement

The nature and extent of community engagement shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the research.

9.4. Engagement with Organizations and Communities of Interest

For the purposes of community engagement and collaboration in research undertakings, researchers and REBs shall recognize Aboriginal organizations, including First Nations, Inuit and Métis representative bodies as communities. They shall also recognize these groups through representation of their members on ethical review and oversight of projects, where appropriate.

9.5. Complex Authority Structures

Where alternatives to securing the agreement of formal leadership are proposed for research on First Nations, Inuit or Métis lands or in organizational communities, researcher should engage community processes and document measures taken, to

enable the REB to review the proposal with due consideration of complex community authority structures.

9.6. Recognizing Diverse Interests within Communities

In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership. Groups or individuals whose circumstances make them vulnerable may need or desire special measures to ensure their safety in the context of a specific research project. Those who have been excluded from participation in the past may need special measures to ensure their inclusion in research.

9.7. Critical Inquiry

Research involving Aboriginal peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit or Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.

9.8. Respect for Community Customs and Codes of Practice

Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and this policy should be identified and addressed in advance of initiating the research, or as they arise.

9.9. Institutional Research Ethics Review Required

Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by institutional REBs, and will not exempt researchers affiliated with an institution from seeking REB approval at their institution, subject to Article 8.1. Prospective research and secondary use of data and human biological materials for research purposes is subject to research ethics review.

9.10. Requirement to Advise the REB on a Plan for Community Engagement

When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise their REB how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement for community engagement, on the basis of an acceptable rationale.

9.11. Research Agreements

Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

9.12. Collaborative Research

As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community.

9.13. Mutual Benefits in Research

Where the form of community engagement and the nature of the research make it possible, research should be relevant to community needs and priorities. The research should benefit the participating community (e.g., training, local hiring, recognition of contributors, return of results), as well as extend the boundaries of knowledge.

9.14. Strengthening Research Capacity

Research projects should support capacity building through enhancement of the skills of community personnel in research methods, project management, and ethical review and oversight.

9.15. Recognition of the Role of Elders and Other Knowledge Holders

Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in the design and execution of research, and the interpretation of findings in the context of cultural norms and traditional knowledge. Community advice should also be sought to determine appropriate recognition for the unique advisory role fulfilled by these persons.

9.16. Privacy and Confidentiality

Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process. The extent to which limited or full disclosure of personal information related to the research is to be disclosed to community partners shall be addressed in research agreements where these exist. Researchers shall not disclose personal information to community partners without the participant's written consent.

9.17. Interpretation and Dissemination of Research Results

Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before the completion of the final report, and before finalizing all relevant publications resulting from the research.

9.18. Intellectual Property Related to Research

In collaborative research, intellectual property rights should be discussed by researchers, communities and institutions. The assignment of rights, or the grant of licenses and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

9.19. Collection of Human Biological Materials Involving Aboriginal Peoples

As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

Secondary Use of Information or Human Biological Materials Identifiable as Originating from Aboriginal Communities or Peoples

Ongoing sensitivity about secondary use of data collected for approved purposes arises from experiences with misrepresentation of Aboriginal peoples; use of data or human biological materials without appropriate engagement with the source community or consent of participants; and lack of reporting to communities on research outcomes. For example, members of Nuu-chah-nulth communities in British Columbia provided blood samples for research on rheumatic disease. They vigorously protested the use of their blood components for subsequent unauthorized genetic research. In addition, there are fears in First Nations communities that access to health data for purposes other than treatment will facilitate unauthorized government surveillance.

When seeking to undertake research involving secondary use of data identifiable as originating from a specific Aboriginal community or segment of the Aboriginal community at large, researchers shall, through community engagement as appropriate, address any potential inadvertent identification of communities, or misuse of traditional knowledge. Requirements regarding the participant's consent for secondary use of identifiable information are addressed in Articles 9.20 and 9.21.

9.20. Secondary use of data and human biological material identifiable as originating from an Aboriginal community or peoples is subject to REB review.

Researchers shall engage the community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary

use where: (a) secondary use has not been addressed in a research agreement and has not been authorized by the participants in their original individual consent; or (b) there is no research agreement; and (c) the data are not publicly available or legally accessible.

Individual consent for the secondary use of identifiable information is required unless the REB agrees that either Articles 5.5 or 5.6, or Articles 12.3 or 12.4 of the TCPS2 may apply.

9.21. Where research relies only on publicly available information, or on legally accessible information as defined in Article 2.2 (of the TCPS2), community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Aboriginal community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community.

9.22. REB review is required where the researcher seeks data linkage of two or more anonymous datasets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Aboriginal community or a segment of the Aboriginal community at large.

10. Qualitative Review

Qualitative research aims to understand how people think about the world and how they act and behave in it. This approach requires researcher to understand phenomena based on discourse, actions and documents, and how and why individuals interpret and ascribe meaning to what they say and do, and to other aspects of the world (including other people) they encounter.

Some qualitative studies extend beyond individuals' personal experiences to explore interactions and processes within organizations or other environments. Knowledge at both an individual and a cultural level is treated as socially constructed. This implies that all knowledge is, at least to some degree, interpretive, and hence, dependent on social context. It is also shaped by the personal perspective of the researcher as an observer and analyst. As a result, qualitative researchers devote a great deal of attention to demonstrating the trustworthiness of their findings using a range of methodological strategies.

10.1. Timing of the REB Review

Researchers shall submit their research proposals, including proposals for pilot studies, for REB approval of its ethical acceptability prior to the start of recruitment of participants, or access to data. Subject to the exceptions in TCPS2 Article 10.5, REB approval is not required for the initial exploratory phase (often involving contact with individuals or communities) intended to discuss the feasibility of the research, establish partnerships, or the design of a research proposal (see TCPS2 Article 6.11).

10.2. Modalities of Expression of Consent

Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

10.3. Observational Studies

In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

10.4. Privacy and Confidentiality in the Dissemination of Research Results

In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed, researchers shall obtain each participant's written consent.

10.5. Qualitative Research Involving Emergent Design

In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection.

Researchers shall consult with the REB when, during the conduct of the research, changes to the data collection procedures may present ethical implications and associated risks to the participants.

11. Research in Emergency Health Situations

11.1. 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 participant or of his/her authorized third party if ALL of the following apply:

- A serious threat to the prospective participant requires immediate intervention.
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant 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 participant.
- The prospective participant 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 participant is known to exist.

11.2. When a previously incapacitated participant 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.

12. SIAST Research Ethics Board

12.1. 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 REB 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 participants 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.

To ensure the independence of REB decision making, senior management shall not serve on the REB. 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, academic & research, in accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. The members shall be knowledgeable of the TCPS2.

12.2. 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, academic & research, 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.

12.3. 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 11.1.

12.4. 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.

12.5. 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.

12.6. 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.

13. Procedural Guidelines for the Review of Research Proposals

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

14. Research Proposal Review Process

14.1. Scholarly Review

14.1.1. 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.

14.1.2. 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.

14.1.3. 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.

14.1.4. 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.

14.2. 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.

14.3. Normal Review Process

14.3.1. The SIAST REB members shall meet face-to-face in order to review submitted proposals. Video-conferencing may be used when REB members are geographically dispersed. 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.

14.3.2. 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.

14.3.3. 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.

14.3.4. 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.

14.3.5. 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
- Participant Recruitment procedures (i.e. advertisements)
- Investigator's brochure
- Available safety information
- Information about payments and compensation available to participants
- 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.

14.4. Delegated Review

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

14.4.1. 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 participant 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 participants, 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.

14.4.2. 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.

14.4.3. This policy requires that all research involving human participants must be submitted to the SIAST REB. If, however, a study is a teaching exercise (i.e., part of a diploma, 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.

14.5. Review of Multi-Jurisdictional Research

It is the responsibility of the researcher to ensure that multi-jurisdictional 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.

Research involving humans that may require the involvement of multiple institutions and/or multiple REBs includes, but is not limited to, the following situations:

- A research project conducted by a team of researchers affiliated with different institutions;
- Several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;

- A research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
- A research project conducted by a researcher who has multiple institutional affiliations;
- A research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations; or
- A research project that researchers working under the auspices of a Canadian research institution conduct in another province, territory, or country.

14.5.1. Adoption of Alternative Review Models

SIAST REB may approve alternative review models for research involving multiple REBs and/or institutions. SIAST remains responsible for ethical acceptability and ethical contact for research undertaken within SIAST jurisdiction.

14.5.2. 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.

14.6. 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 participants must be reported to the SIAST REB. Significant changes will require the submission of a revised application for ethics approval.

14.6.1. 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.

14.6.2. 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.

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

14.7. 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.

15. Decisions of the SIAST REB

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

- 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.

15.1. 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.

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

15.3. 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.

15.4. 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.

16. 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.

17. 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 provost and 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 provost and 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

- 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.

18. Annual Report Prepared by REB

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

19. Adverse Events Reports

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

20. 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.

20.1. 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.

20.2. 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

- 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.

20.3. Interpretation

Questions of interpretation or application of this policy or its procedures shall be referred to the associate vice-president, academic & research 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.

21. 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.