Sheridan | Get Creative	THE SHERIDAN COLLEGE INSTITUTE OF TECHNOLOGY AND ADVANCED LEARNING	
TITLE: Human Participants Policy		
Date of Approval: June 15, 2005 **Effective Date:**	**Mandatory Review Date:**	**Approved By:** ☐ Board of Governors ☐ President's Council ☐ Senate

1. PURPOSE

The mission of the Sheridan Research Ethics Board and this policy is to ensure that research affiliated with Sheridan involving human participants meets the highest Ethical Standards. To do this, Sheridan follows the guidelines set out in the Tri-Council Policy Statement on Ethics Conduct Involving Humans (2014).

1.1 Principles:

Sheridan supports a proportionate approach to human participants research review based on the general principle that the more invasive the research, the greater should be the care in assessing the research. Sheridan recognizes the following universal principles to guide ethical research conduct:

a) Respect for human dignity
b) Respect for free and informed consent
c) Respect for vulnerable persons
d) Respect for privacy and confidentiality
e) Respect for the law
f) Respect for fairness and equity
g) Respect for trustworthiness and honesty
h) Protection of participants and researchers from injury or harm

Research proposals must demonstrate that appropriate methods will be used to protect the rights and interests of human participants in the conduct of research.

2. POLICY SCOPE

This policy applies to individuals associated with Sheridan in any capacity whatsoever conducting research involving human participants. Anyone working under the aegis of Sheridan engaging in research, using College facilities, approaching Sheridan personnel (staff or students) or seeking approval or endorsement from Sheridan for research involving humans must adhere to the highest level of ethical standards. This includes research conducted in other jurisdictions or countries.

2.1 Research Proposals for Research Involving Human Participants Shall Be Subject To Ethical Review

Unless specifically excluded (see *Research Not Subject to Ethical Review* in the following section), the requirement for ethical review applies to research proposals involving human participants whether or not financial support is involved and whether or not an ethical review is required by another agency.

- Human participants refers to living individuals and to groups of living individuals, such as publicly identifiable social, ethnic, religious, or economic groups.
- Human participants also includes human biological materials as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.
- Research means any gathering of information from or about human participants. This includes but is not limited to physical, sociological, or psychological tests and measurements, surveys, non-intrusive systematic observation, interviews, focus groups, and the study of recorded data from previous studies, databases; and archives, in which it is possible to identify living individuals.

2.2 Research Not Subject To Ethical Review

The following kinds of research proposals are specifically exempted from the need for ethical review*:

a) Quality assurance studies, performance reviews, questionnaires concerning employee performance or course content distributed to a class by instructors or others within normal educational requirements in which there is no research component to the activity.

b) Research conducted by Sheridan where such research is conducted to meet external reporting requirements or to facilitate the management of the institution.

c) Research or other study of the published writing or other public utterances of human participants.

d) Research where data are exclusively in the public domain, provided that either:

i) The information is legally accessible to the public and appropriately protected by law (i.e. information made public by law or regulation in a specific form for a specific purpose), or

ii) The information is publicly accessible (i.e., any existing stored documentary material, records or publications which may or may not include identifiable information) and there is no reasonable expectation of privacy.

iii) But there are certain publicly accessible digital sites where there is a reasonable expectation of privacy and so REB review would be required, e.g. Internet chat rooms and self-help groups with restricted membership

e) Research involving the observation of people in public places, where

i) It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;

ii) Individuals or groups targeted for observation have no reasonable expectation of privacy; and

iii) Any dissemination of research results does not identify specific individuals.

f) Research that relies exclusively on secondary use of anonymous human information or anonymous human biological materials, so long as the research process does not generate identifiable information.

i) In this context, “secondary use” means “the use in research of information or human biological materials originally collected for a purpose other than the current research purpose.” (TCPS 2, 2014, p. 196)

All other researchers must complete the statement of Ethical Review, submit it to Sheridan Research and receive confirmation from Sheridan Research that further

ethical review is not required prior to recruiting participants and prior to commencing research.

**Where there is a potential element of research, the project will be reviewed by the SREB, and if in doubt, researchers must consult the SREB before proceeding.*

3. DEFINITIONS

Research Ethics Board: "A body of researchers, community members, and others with specific expertize (e.g. in ethics, in a relevant discipline) established by an institution to review the ethical acceptability of all research involving humans conducted with in the institution's jurisdiction or under its auspices." (TCPS 2, 2014, p.217)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) is a joint policy of Canada's three Federal Research Funding Agencies: The Canadian Institutes of Health Research (CIHRC), The Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Council of Canada (SSHRC).This Policy is intended to guide Canadian researchers, in Canada and abroad, involving humans (TCPS 2, 2014).

To be eligible to receive funding and conduct funded research from any of these 3 funding agencies, an institution must agree to be in compliance with the TCPS 2 and ensure that research conducted under their auspices adhere to these policy guidelines (TCPS 2, 2014)

4. POLICY STATEMENT

4.1 **Sheridan Research Ethics Board**

4.1.1 This policy should be applied in conjunction with Sheridan's Applied Research Policy, Research Integrity Policy and Applied Research Intellectual Property Policy.

4.1.2 Sheridan recognizes the importance of the preservation of human dignity and the ethical treatment of any human participants involved in research.

Therefore:

a) Sheridan shall appoint and maintain a research ethics board which shall establish and monitor the implementation of policies regarding the treatment of human participants.
b) The Sheridan Research Ethics Board (SREB) has responsibility for all research conducted with human participants at The Sheridan College Institute.
c) The Sheridan Research Ethics Board (SREB) must approve all research projects involving humans before recruiting participants for the research.
d) Research involving naturalistic observation of participants normally requires SREB review.
e) If warranted in future research projects, human remains, tissues, biological fluid, embryos or fetuses will be reviewed by the SREB.
f) Approval of projects meeting criteria of minimal risk may be delegated by SREB to the SREB Chair or their designate on the SREB.

g) The SREB will normally only allow research to be carried out only after the voluntary free and informed consent of the participant or his/her authorized third party has been given.
h) Researchers shall provide full and frank disclosure of all information relevant to free and informed consent.
i) In the event of an institutional conflict of interest, the SREB shall consider whether it should be disclosed to prospective participants as part of the consent process.
j) All participants capable of providing consent must understand the consent provisions and, generally, must sign appropriate (and understandable) consent forms. (See Appendix "A".)
k) Where potential participants are judged incapable of providing consent, the researcher must obtain appropriate consent from a legal guardian or authorize representative prior to their involvement in the research project. Information regarding the appropriate form of consent will be available from Sheridan Undergraduate
Research.
l) Ethical considerations around research involving those who are not competent to give free and informed consent on their own behalf must seek to balance the vulnerability that arises from their incompetence with the injustice that would arise from their exclusion from the benefits of the research.
m) Researchers must disclose to participants any material incidental findings discovered in the course of research. Incidental findings which are material are those which have significant welfare implications for the participant

4.2 Delegated Approval

4.2.1 Only proposed projects that meet the criteria of "minimal risk" (as defined in Appendix B) may be provided with a delegated review process by the SREB Chair or their designate on the SREB. Decisions related to projects of minimal risk will be reported and recorded at these meetings. Reports of the delegated review process are provided to the full board.

4.2.2 Actions and decisions of a delegated reviewer(s) must be well documented and formally reported to the full SREB in a timely and appropriate manner. When delegated review is conducted by non-members of the SREB, this formal report shall be made through the Chair of the SREB.

4.3 Research Involving the First Nations, Inuit and Metis People of Canada

4.3.1 Community Engagement in Aboriginal Research

Researchers must seek engagement with the relevant community when their research is likely to affect the welfare of an Aboriginal community (community in this context means a collectivity with a shared identity or interests that has the capacity to act or express itself as a collective). Engagement here means a collaborative, interactive relationship between the researcher and the community which can take a number of forms such as review and approval, joint planning or dialogue with a representative group. The nature and extent of engagement must be determined jointly by the researcher and the relevant community. Conditions under which engagement is required include:

a) Research conducted on First Nations, Inuit or Metis land
b) Recruitment criteria that include Aboriginal identity as a factor

c) Research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics
d) Research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of research data
e) Interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture

However, where research relies exclusively on publicly available or legally accessible information, community engagement is not required.

4.3.2 Respect for First Nations Governing Authorities

Where a proposed research project is to be conducted on land under the jurisdiction of a First Nations, Inuit or Metis authority, researchers shall seek the engagement of formal leaders of the community. In advance of recruiting and seeking consent of individuals in such situations, a researcher must gain approval from both the SREB and any responsible community body recognized by the formal Aboriginal authority.

4.3.3 Respect for Community Customs and Codes of Practice

Researchers must inform themselves about and respect the relevant customs and codes of research practice that apply in the community which their research affects.

4.3.4 Plan for Community Engagement

A researcher who proposed a project which is expected to involve Aboriginal participants must advise the SREB how they have engaged, or intend to engage, the relevant community. In the alternative, a researcher may seek SREB approval for an exception to the requirement of community engagement on the basis of an acceptable rationale.

4.3.5 Privacy and Confidentiality

Researchers and community partners must address privacy and confidentiality early on in the engagement process. Where research agreements exist, they must specify the extent to which disclosure of personal information related to the research is to be disclosed to the community partners. Researchers must not disclose personal information to community partners without the participant's consent. Research must be designed to include safeguards for participant privacy and measures to protect the confidentiality of all data collected, taking into account that coding data may be insufficient to mask identities where research takes place in small, dense communities.

4.3.6 Collection of Human Biological Materials Involving Aboriginal Peoples

Where human biological materials and associated data are to be collected as part of research involving Aboriginal peoples, researchers must address the issue of rights and proprietary interests of individuals and communities, to the extent they exist, in their research agreements.

4.3.7 Secondary Use

Prior to initiating secondary use of data or human biological materials, researchers must engage the community from which the data or materials originate in the following circumstances:

a) Secondary use has not been addressed in a research agreement or authorized by the participants in their original consent
b) There is no research agreement and the data are not publicly available or legally accessible

SREB 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.

4.4 Scholarly Review as Part of Ethics Review

The SREB shall avoid duplicating previous professional peer-review assessments unless there is a defined reason to do so. They may request the researcher to provide them with the full documentation of those reviews. In evaluating the merit and the scholarly standards of a research proposal, the SREB should not reject research proposals because they are controversial, challenge mainstream thought or offend powerful or vocal interest groups. The primary tests to be used by SREB should demonstrate ethical probity and high scientific and scholarly standards.

4.5 Decision Making Process

4.5.1 Research proposals shall be forwarded to the members of the SREB at least ten (10) working days in advance. If it is not sent to delegated review, the SREB shall hold a face- to-face meeting to review the proposed research. (Full review is the default process.) Quorum for such meetings shall be established when at least two-thirds of appointed voting members are present and that those members in attendance are representative of the membership requirements of the SREB.

4.5.2 The SREB will use the following steps in order to make a decision:

a) Full discussion by the board, without the researcher present
b) Follow up with the researcher to address all questions and concerns raised by the SREB, either in person or in writing at the discretion of SREB
c) SREB consensus is sought through further discussion and deliberation until a decision is reached.

4.5.3 The SREB shall make an effort to reach consensus, however if a consensus cannot be reached, the SREB shall not approve any proposal which receives more than one dissenting vote of the members eligible and present.

4.5.4 The SREB shall assign each application to one of the following categories: accepted, conditionally accepted subject to revisions, or rejected.

4.5.5 Applicants will be provided a written record of the decision, including reasons for the classification.

4.5.6 Researchers have the right to request reconsideration of unfavorable decisions affecting their research projects made by the SREB. The SREB shall provide a reasonable opportunity for the researcher to be heard, explanation of the reasons for their decisions and the opportunity for rebuttal, fair and impartial judgment and reasoned and written grounds for their decisions. After a negative decision, researchers may request that the SREB reconsider the decision. If an agreement cannot be reached, then an appeal may be initiated.

4.5.7 A resubmitted application that was rejected a second time may be appealed to the President's office within ten (10) working days of receipt of the decision. An appeal board will be established as a standing committee whose membership requirement will be the same as that for the SREB. (I.e. that will be composed of member(s) who have broad expertise in the methods or in the areas of research that are covered by the SREB; is knowledgeable in ethics; has no affiliation with Sheridan, but is recruited from the community served by Sheridan).

4.6 Ongoing Research

4.6.1 Ongoing research is subject to continuing ethics review. The SREB must be notified of any significant proposed changes to the research plan or research protocol before such changes are implemented. Ethics approvals have a maximum term of one (1) calendar year from the date of approval. Extension of that term requires a written request from the researcher to the SREB. The SREB must be notified when an approved project concludes. At minimum, continuing ethics review shall consist of an annual status report for multi-year research projects. Researchers working on projects which last less than one year shall submit an end-of-study report upon completion of the project.

4.6.2 Researchers must report to the SREB any unanticipated issue or event which arises during the course of research that may increase risk to participants or may have other ethical implications relevant to the welfare of participants. Depending on the severity of the issue, the SREB may require the researcher to adjust or suspend the research program.

4.6.3 The SREB must maintain records of its reports and decisions related to unanticipated issues or changes to approved research, including details of how the researcher dealt with or proposed to deal with the situation, and the SREB's response or decision.

4.7 Research in Emergency Health Situations

4.7.1 Research in Emergency Health Situations shall be conducted only if it addressed the emergency needs of the individuals involved. The SREB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or his/her third party authorization when all of the following apply:

a) There is a serious threat to the prospective participant that required immediate intervention.

b) The research offers a real possibility of direct benefit in comparison with the standard

care.
c) Risk or harm is not greater than that involved in standard care or is clearly justified by the direct benefits to the participant.
d) The participant is unconscious or lacks capacity to understand.
e) Third party authorization cannot be obtained in sufficient time despite documented efforts to obtain authorization.
f) No relevant prior directive by the participant is known to exist.

4.8 Multi-Jurisdictional Research

This section applies to research with human participants involving multiple institutions and/or REBs.

4.8.1 Where SREB-approved research is conducted outside of Ontario, researchers may need to obtain permission from a responsible agency (if one exists) to access the site and/or participants. In such a circumstance, the researcher must promptly inform the SREB whether or how the researcher will seek permission to proceed with the research at that site and with the target participants.

4.8.2 In the circumstances described in 4.7 if there is no established ethics review mechanism at the research site then the researcher must inform the SREB of that absence and must report to the SREB the researcher's efforts to identify other suitable local review mechanisms.

4.8.3 If no suitable ethics review mechanisms exist at the research site, the researchers and SREB must apply the core principles of the Tri Council Policy Statement 2: respect for persons, concern for welfare and justice (see the TCPS2 Chapter 1 for more detail on core principles). Absence of a local ethics review mechanism should not prevent the SREB from approving the project. Instead, researchers should familiarize themselves with and respect relevant cultural practices while minimizing risk to human participants, and must inform the SREB of their strategy to do so.

4.8.4 When conducting research outside of Ontario, researchers must provide the SREB with:

a) Relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist;
b) The names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site; and
c) Relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the SREB

4.9 Fairness and Equity in Research

4.9.1 Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age unless there is a valid reason for exclusion.

4.9.2 Women shall not be inappropriately excluded from research solely on the basis of gender, sex, reproductive capacity, pregnancy or breastfeeding. Researchers require valid reasons to exclude women from their research.

4.9.3 Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage. Researchers require valid reasons to exclude children from their research.

4.9.4 Elderly people shall not be inappropriately excluded from research solely on the basis of their age or developmental stage. Researchers require valid reasons to exclude elderly people from their research

4.9.5 Subject to applicable legal requirements, individuals who lack capacity to consent to research shall not be inappropriately excluded from research. Where a researcher seeks to involve such an individual in research, the researcher must satisfy the SREB that:

a) Item #19 of Appendix A to this Policy ("Standards for Assessing a SREB Application") is fully satisfied; and
b) The research question can be addressed only with participants within the identified group; and one of the following two items is satisfied:
c) The research does not expose the participants to more than minimal risk without the prospect of direct benefits to them; OR
d) Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

5. SANCTIONS/ACTIONS/APPEALS

Any allegations of breach of this policy will be handled according to the Procedure for Handling Allegations of Research Integrity Policy Violations, located within the Research Integrity Policy.

6. RELATED DOCUMENTATION (ADDITIONAL POLICIES/PROCEDURES/FORMS)

- Tri-Council of Canada Policy Statement (2014)
- APPENDIX A: Standards for Assessing a Sheridan Research Ethics Board (SREB) Application
- APPENDIX B: Application Submission Checklist
- APPENDIX C: Sheridan Research Ethics Board Application form
- APPENDIX D: Suggested Elements for Letters of Invitation and Research Consent Forms