

**SHERIDAN COLLEGE INSTITUTE OF TECHNOLOGY
AND ADVANCED LEARNING**

BOARD OF GOVERNORS POLICY MANUAL

POLICY: HUMAN SUBJECTS POLICY

POLICY STATEMENT

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

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

Therefore:

- Sheridan shall appoint and maintain a research ethics board who shall establish and monitor the implementation of policies regarding the treatment of human participants.
- The Sheridan Research Ethics Board (SREB) has responsibility for all research conducted [with human participants](#) at The Sheridan College Institute.
- The Sheridan Research Ethics Board (SREB) must approve all research projects involving humans before recruiting participants for the research.
- Research involving naturalistic observation of participants normally requires SREB review.
- If warranted in future research projects, human remains, tissues, biological fluid, embryos or fetuses will be reviewed by the SREB.
- Approval of projects meeting criteria of minimal risk may be delegated by SREB to the SREB Chair or their designate on the SREB.
- 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.
- Researchers shall provide full and frank disclosure of all information relevant to free and informed consent.
- All participants capable of providing consent must understand the consent provisions and, generally, must sign appropriate (and understandable) consent forms. (See Appendix "A".)
- Where potential participants are judged incapable of providing consent, the researcher must obtain appropriate consent from a legal guardian prior to their involvement in the research project. Information regarding the appropriate form of consent will be available from Sheridan [Applied](#) Research.
- 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.

PRINCIPLES/GUIDELINES

Sheridan supports a proportionate approach to human subjects 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 participants in the conduct of research.

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.

Research Proposals for Research Involving Humans Shall Be Subject To Ethical Review

Unless specifically excluded (see *Research Not Subject to Ethical Review* on the next page), 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 subjects/participants refers to living individuals and to groups of living individuals, such as publicly identifiable social, ethnic, religious, or economic groups.
- 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.

Research Not Subject To Ethical Review

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

1. 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.
2. Research conducted by Sheridan where such research is conducted to meet external reporting requirements or to facilitate the management of the institution.
3. Research or other study of the published writing or other public utterances of human subjects.
4. Research where data are in the public domain.
5. Naturalistic observation of participants seeking visibility at public events.

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.*

EXPEDITED APPROVAL

Proposed projects that meet the criteria of “minimal risk” (as defined in Appendix B) may be provided with an Expedited Approval 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 expedited review process are provided to the full board.

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.

Responsible Executive:

Contact: Dean, Applied Research
Department: Sheridan Applied Research
Telephone: 905-815-4232

***Policy approved by the Sheridan College Institute Board of Governors: June 15, 2005
Revised and approved for Tri-Council: July 31, 2007***

**SHERIDAN COLLEGE INSTITUTE OF TECHNOLOGY
AND ADVANCED LEARNING**

ADMINISTRATIVE PROCEDURE

**PROCEDURE #1: SHERIDAN RESEARCH ETHICS BOARD
RESPONSIBILITIES**

RELATED POLICY: HUMAN SUBJECTS POLICY

PROCEDURE STATEMENT

Sheridan shall maintain a research ethics board. The Sheridan Research Ethics Board (SREB) exercises the authority of the President in matters concerning research on human subjects and is responsible to the President in all matters concerning such research under the aegis of Sheridan.

The purpose of the SREB is both to educate the Sheridan community as to ethical issues in research and to review research proposals to ensure ethical research behaviour. The SREB will meet at least once per semester, and as required to review proposed research that is not delegated to expedited review. The SREB shall maintain written documentation of all of its activities that clearly outlines the SREB's decisions and any dissents, and the reasons for them. The minutes will be accessible to authorized representatives of the institution, research and funding agencies.

The SREB shall consist of at least five members (both men and women) of whom:

- a. at least two members have broad expertise in the methods or in the areas of research that are covered by the SREB;
- b. at least two members are knowledgeable in ethics;
- c. at least one member has no affiliation with Sheridan, but is recruited from the community served by Sheridan (meaning someone not formally associated with Sheridan at the time the SREB is constituted. For the sake of clarity, an alumnus of Sheridan not otherwise associated with Sheridan could be a representative from outside of Sheridan.)
- d. where biomedical research may be contemplated, a person knowledgeable in that law would first be appointed to the SREB.
- e. The Dean, Applied Research attends all meetings as an ex-officio resource to its members, but is not counted in the quorum, does not have voting rights and does not engage in the decision making process.

Members of the SREB will be nominated by the Dean, Applied Research and appointed by the President. The Chair will be nominated by the SREB and appointed by the President. The Board may add temporary members when required to provide relevant expertise not available among the SREB's regular members. His or her input is a form of consultation that may or may not be considered in the final decision of the SREB. Temporary members will not be counted in the quorum or have voting rights.

The SREB has the authority to make the rules and regulations necessary to implement this policy where research involving human subjects is carried out. The SREB can approve, reject, propose modifications to, or terminate any proposed research involving human participants which is conducted within or by members of the institution, including the authority to delegate to academic sectors the ability to carry out and approve the ethical review of student projects where research involving human participants is conducted under faculty supervision as part of approved Sheridan courses. However, the SREB always bears sole responsibility for ethical approval.

Sheridan Research shall provide ongoing education to the Sheridan research community on research ethics issues.

Researchers and SREB members shall disclose actual, perceived or potential conflicts of interest to the Board. If the SREB is reviewing research in which a member of the Board has a personal interest in the research under review, that member will not be present when the SREB is discussing or making its decision.

The Standards for Assessing a Research Ethics Board Application are outlined in Appendix A of this document.

PRINCIPLES

The SREB shall use a proportionate approach to research review based on the general principle that the more invasive the research, the greater should be the care in assessing the research. Reviews of proposals involving "minimal risk" shall normally involve expedited reviews.

The standard of minimal risk to participants is commonly defined as follows: If potential participants can reasonably be expected to regard the probability and magnitude of possible harm implied by participation in the research to be no greater than those encountered in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny.

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.

Decision Making Process

Research proposals shall be forwarded to the members of the SREB at least 10 days in advance. If it is not delegated to expedited 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.

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

- full discussion by the board, without the researcher present
- 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
- SREB consensus is sought through further discussion and deliberation until a decision is reached.

The SREB shall make an effort to reach consensus, however if a consensus cannot be reached, there shall be no more than one dissenting vote of the members eligible and present.

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

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

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.

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).

Ongoing Research

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.

Research in Emergency Health Situations

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 with the free and informed consent of the participant or his/her third party authorization when all of the following apply:

- There is a serious threat to the prospective participant that required immediate intervention.
- The research offers a real possibility of direct benefit in comparison with the standard care.
- Risk or harm is not greater than that involved in standard care or is clearly justified by the direct benefits to the participant.
- The participant is unconscious or lacks capacity to understand.
- Third party authorization cannot be obtained in sufficient time despite documented efforts to obtain authorization.
- No relevant prior directive by the participant is known to exist.

Responsible Executive:

Contact: Dean, Applied Research
Department: Sheridan Applied Research
Telephone: 905-815-4232

**SHERIDAN COLLEGE INSTITUTE OF TECHNOLOGY
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ADMINISTRATIVE PROCEDURE

PROCEDURE #2: SUBMISSION PROCEDURE FOR ETHICAL REVIEW

RELATED POLICY: HUMAN SUBJECTS POLICY

PROCEDURE STATEMENT:

Anyone associated with Sheridan conducting Applied Research and anyone that is conducting Applied Research that is or could be associated with Sheridan must:

- a) Submit an Application for Ethical Review to the Sheridan Research Ethics Board (SREB) (see Appendix B), unless excluded as described in the Policy Scope, before beginning implementation of a project or acquiring resources for it. This applies to all projects whether or not special financial support is involved and whether or not an ethical review is required by another agency.

Students assisting in research projects under faculty supervision must ensure that they adhere to the ethical review policy when reporting to the academic manager of their program or course or an appointed designate.

Everyone else must submit an application for ethical review to the Chair of the SREB through Sheridan Research.

- b) Submit a signed* Informed Consent Form (see Appendix C) that includes, but is not limited to the following:
 - Title of research project
 - Date of ethical approval
 - Identity of researcher(s)
 - Sources of funding
 - Purpose of research
 - Description of research
 - Explanation of potential harms/benefits
 - Confidentiality statement
 - Voluntary participation statement
 - Explanation of the right to withdraw and specific steps required
 - Consent explanation and signature

** Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.*

- c) Advise the SREB of any change to the research procedures for a project as soon as a need for change is identified, and to delay implementation and submit a new Application for Ethical Review if the SREB decides the change, or a series of changes, is substantial enough to warrant a new approval process.
- d) Be familiar with and guided by applicable legislation and current professional standards and ethical guidelines (e.g., The Tri-Council Policies Dealing with Integrity in Research).
- e) Follow all procedures established by legislation, this policy, and the SREB.
- f) Maintain appropriate stewardship of research data during the agreed upon time period (approved by the Sheridan Research Ethics Board) and destroy all data using appropriate methods when that time period ends.

Responsible Executive:

Contact: Dean, Applied Research
Department: Sheridan Applied Research
Telephone: 905-815-4232

SHERIDAN RESEARCH HUMAN SUBJECTS POLICY – APPENDIX A

Standards for Assessing a Sheridan Research Ethics Board (SREB) Application

The Sheridan College Institute of Technology and Advanced Learning

1. It must be clear who is doing the research, what their affiliation with Sheridan is, and how they can be contacted.
2. Potential participants should be aware of any sources of funding for the project.
3. An appropriate administrator must be aware of this research and its ethical implications.
4. The purpose and importance of the research must be identified.
5. The research process must be described.
6. Anticipated methods of dissemination of the results must be disclosed.
7. Previous SREB reviews must be declared and the results submitted to the SREB.
8. Conflicts of interest of any kind must be declared.
9. Relationships regarding the exercise of authority with the participants must be disclosed.
10. The level of risk must be identified. Only studies involving minimal risk may be considered for expedited review. If not a minimal risk study, then a complete presentation to the SREB must be made.
11. If deception is being used, it must be completely justified and approved by the SREB.
12. The potential participants of the study, the method of selection, and what participants will have to do must be identified.
13. In considering research involving naturalistic observation, researchers and SREB should pay close attention to the ethical implications of such factors as the nature and environment of the activity being observed and the means of recording observations.
14. Research involving vulnerable persons will only be conducted if the research questions can only be addressed within that identified group and the research does not expose them to more than minimal risk without the potential for direct benefits.
15. A Sheridan “Informed Consent Form” is generally submitted in writing and signed by the participant or authorized third party describing the research, purpose, importance, participation, risks, benefits, compensation, protection of data, guarantees of anonymity (if appropriate), an explicit statement as to the voluntariness of participation and an explanation of the process for withdrawal.

16. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

17. The SREB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the SREB finds and documents that the:

- research involves no more than minimal risk to the participants
- waiver is unlikely to adversely affect the rights and welfare of the participants
- research could not practicably be carried out without the waiver or alteration
- participants will be provided additional pertinent information as appropriate and/or the waived or altered consent does not involve a therapeutic intervention.

18. For research involving incompetent individuals, the SREB shall ensure that, as minimum, the following conditions are met:

- (a) The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the participants' best interests will be protected.
- (b) The authorized third party may not be the researcher or any other member of the research team.
- (c) The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent participant.
- (d) When a participant who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought in order to continue participation.
- (e) Where 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 or her participation.

SHERIDAN RESEARCH HUMAN SUBJECTS POLICY – APPENDIX B

Application for Ethical Review of Research

The Sheridan College Institute of Technology and Advanced Learning

Completion of the following information is important in order to provide the potential participant all information relevant to free and informed consent:

I. Applicant Information

Date: _____

Project Title: _____

Name of Principal Investigator: _____

Faculty [] Staff [] Student []

Other [] Centre/Institute: _____

Department: _____

Room: _____ Email: _____

Phone: _____ Fax: _____

Names and contact information of other Investigators or Agencies: _____

II. Signatures

Your signature indicates that you are familiar with and agree to abide by all policies, procedures, regulations, and laws governing ethical conduct of research at Sheridan. Furthermore, your signature attests to the fact that you believe all the information provided in this application is true.

Principal Investigator: _____ Date: _____

The signature of your administrator indicates that the administrator is aware of the research study and its ethical implications.

Academic Administrator: _____ Date: _____

III. Level of Risk

The standard of minimal risk is defined as follows:

If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.

Please note, the designation of minimal or non-minimal risk only affects the way the application is reviewed, *not the substance* of the review.

Based on this definition, do you believe your research qualifies as minimal risk research?

No Yes

(Briefly explain your answer.)

Does this study involve any form of deception?

No Yes (provide details)

(Briefly explain need for deception and when truth will be revealed.)

Has this research been reviewed or rejected by any other ethical review board or process?

No Yes (provide details):

(Briefly explain previous review.)

Does the study collect personal information about an identifiable individual?

No Yes (provide details):

(Briefly describe personal information that will be collected.)

IV. Project Information

Proposed start date:

Completion date:

1. Purpose of the research

(Briefly describe the purpose of the study, the objectives, and why it is being done.)

2. Why is this research important?

3. Description of participants.

(Who will be included in this study, how will you recruit them; and why were they selected for inclusion in this study?)

4. How much time will be required to participate?

5. What will participants be required to do?

(Provide copies of questionnaires, tests, interview questions, etc.)

- be interviewed
- complete a questionnaire
- take a test
- participate in a group interview
- be observed
- provide human tissue (blood, hair, urine, etc.)
- provide access to records
- Other (specify):

6. Describe the research process.

(How will participants be recruited? Where is the research to be conducted? [E.g. in class, on campus, by phone, on internet, etc.]; what methods/tools will be used? [E.g. planned treatments, interventions, or manipulations, data analysis, etc.]

7. Describe how you plan to deal with informed consent and voluntary participation. Attach a copy of your informed consent form to this application.

(What steps will you take to insure that the potential participants can make an informed choice about participation; understand that they do not have to participate; and can withdraw at any time, for any reason, without negative consequences?)

8. Do you have a power relationship with the participants?

(E.g. Are you in a teacher-student or employer-employee relationship with the participants?)

No Yes

(If yes, how will you avoid exercising undue influence over the participants?)

9. Describe potential benefits and harms, as well as how potential harms will be mitigated.

(Describe all foreseeable harms to participants, including physical, psychological, emotional or social, and how they will be mitigated.)

10. Describe potential risks to the Sheridan College Institute, and how they will be mitigated.

(Describe all foreseeable harm to Sheridan including financial, legal and negative implications for workplace culture, public perception, etc., and how they will be mitigated.)

11. Will anonymity of participants be protected?

No Yes

(If so, how? If not, why?)

12. Describe confidentiality of data and data storage practices.

(Describe how participants will know who will have access to the research data, whether or not it will be published, how confidentiality will be protected, what happens to a person's data if he/she withdraws from the study, how long the data will be maintained and when the data will be destroyed.)

13. How do you anticipate disseminating your results?

- directly to participants
- class presentation
- published article
- Internet
- conference presentation
- Other (specify)

14. Is there anything else the Sheridan Research Ethics Board should know about this study?

15. Please attach a completed and signed **Informed Consent Form and copies of any questionnaires, tests, interview questions, etc. that will be used in the research.***

** Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.*

SHERIDAN RESEARCH HUMAN SUBJECTS POLICY – APPENDIX C

Suggested Elements for Letters of Invitation and Research Consent Forms

The Sheridan College Institute of Technology and Advanced Learning

Remember that consent is a two-way process – obligations for the researcher as well as consent to participate. Your signature is as important as the participant's. Offer one copy to the participants and retain one for your records.

You are being invited to participate in a study entitled (*TITLE*) that is being conducted by (*INVESTIGATOR(S) NAME(S)*). (*INVESTIGATOR'S NAME*) is a (*RELATIONSHIP WITH SHERIDAN ... E.G. FACULTY MEMBER, STUDENT, ETC.*) in the (*DEPARTMENT NAME*) at Sheridan and you may contact (*HIM/HER/THEM*) if you have further questions by calling (*PHONE NUMBER*).

The purpose of this research project is (*INCLUDE THE INFORMATION FROM QUESTION #1 IN THE ETHICS APPLICATION HERE*).

Research of this type is important because (*INCLUDE THE INFORMATION FROM QUESTION #2 IN THE ETHICS APPLICATION HERE*).

The project is being funded by (*INCLUDE NAMES OF FUNDING AGENCIES, ETC.*)

You are being asked to participate in this study because (*INCLUDE THE INFORMATION FROM QUESTION #3 IN THE ETHICS APPLICATION HERE*).

If you agree to voluntarily participate in this research, your participation will include (*INSERT THE INFORMATION FROM QUESTIONS #4 & #5 IN THE ETHICS APPLICATION HERE*).

[You must include one of the following:]

There are no known or anticipated risks to you by participating in this research. OR

There are some potential risks to you by participating in this research and they include (*INSERT THE APPROPRIATE INFORMATION FROM QUESTION #9 IN THE ETHICS APPLICATION HERE*).

The potential benefits of your participation in this research include (*INSERT THE APPROPRIATE INFORMATION FROM QUESTION #9 IN THE ETHICS APPLICATION HERE*).

[If applicable include the following]:

As a way to compensate you for any inconvenience related to your participation, you will be given (*DESCRIBE ANY FORM OF PAYMENT, CREDIT, ETC.*). It is important for you to know that it is unethical to provide undue compensation or inducements to research participants.

In terms of protecting your anonymity (*INCLUDE THE APPROPRIATE INFORMATION FROM QUESTION #11 IN THE ETHICS APPLICATION HERE*).

Your participation in this research must be completely voluntary. If you decide to participate, you may withdraw at any time without any consequences or any explanation. If you do withdraw from the study your data will (*INCLUDE THE APPROPRIATE INFORMATION FROM QUESTION #12 IN THE ETHICS APPLICATION HERE*).

It is anticipated that the results of this study will be shared with others in the following ways (*INCLUDE THE INFORMATION FROM QUESTION #13 IN THE ETHICS APPLICATION HERE*).

In addition to being able to contact the researcher(s) at the above phone number(s), you may verify the ethical approval of this study, or raise any concerns you may have, by contacting either the Director, Sheridan Research (905-815-4232) or (*INVESTIGATOR(S) NAME(S) and CONTACT INFORMATION*).

Principal Investigator (*INSERT CONTACT INFORMATION HERE*)

Researcher Signature

Date

Your signature below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researcher(s).

Participant Signature*

Date

OR

Authorized Representative Signature**

Date

**Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.*

***Free and informed consent must be obtained from an authorized representative for someone who is not legally competent to consent to be a research participant.*

Subject to applicable legal requirements.