



# SENECA COLLEGE OF APPLIED ARTS AND TECHNOLOGY

## Policy and Procedures for Ethical Conduct for Research Involving Human Participants

### Policy Statement

Approved by the Board of Governors March 30, 2005

Consistent with the Mission of Seneca College, research conducted by the College is primarily applied research (Strategic Plan 2004-2009).

Seneca College has a responsibility to safeguard the rights and well-being of students, faculty and staff, and other members of the Seneca community. It is the policy of Seneca College that all research projects associated with the College will adhere to accepted ethical, legal and integrity standards, consistent with the Tri-Council Guidelines.

The primary responsibility for ensuring that the rights and interests of all human participants involved in research are respected rests with the individuals involved in these research activities. Seneca faculty and staff and all other persons conducting research associated with the College are responsible for the integrity of their work and upholding the principles and responsibilities as stated in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (June, 2003).

The College assumes responsibility for professional development opportunities specifically related to ethical conduct for research involving human participants for all Seneca faculty and staff.

### Definition

Research involving human participants in this context refers to research conducted within the Seneca College community or associated with Seneca College, where human beings participate in research studies, or where databases of information about them will be used as part of a research study. Data collection that is part of the core mandate and normal operations of the college is normally not considered to be research studies.

### Underlying Principles

The College is committed to ensuring that the rights of all participants in research involving individuals associated with Seneca College are safeguarded. In general, this includes but is not limited to employees, students, parents/guardians of minors, alumni and clients, partners and patients whether the research is carried out locally or in other jurisdictions or countries.

This includes, but is not limited to, the following rights:

**Respect for Human Dignity** – is the cardinal principle of research ethics. This includes protection of the “multiple and interdependent interest of the person” (Tri-Council Policy Statement, p. 1.5), protecting their integrity and safeguarding them from physical, psychological or cultural harm.

**Respect for Free and Informed Consent.** This includes a clear disclosure of the nature of the research study, its potential impact on the participant, voluntary participation, and the right to withdraw from

participation or refrain from answering any question(s) that are deemed by the participant to be intrusive, without explanation or penalty.

**Respect for Vulnerable Persons.** This refers to a high ethical obligation towards vulnerable persons, (such as children and persons who are developmentally challenged) that is, those whose capacity to make informed decisions is diminished makes them vulnerable. This may require special procedures, such as requiring the written consent of a legally responsible adult to protect these individual's interests.

**Respect for Privacy and Confidentiality.** This includes the protection of access to, control of and dissemination of personal information. It means that participants are assured of confidentiality, anonymity and/or non-identifiability, unless they consent to disclosure in an informed, written authorization.

**Respect of Justice and Inclusiveness.** This means the ethics review process has fair methods, standards and procedures for reviewing research proposals, and that "no segment of the population should be unfairly burdened with the harms of research" (Tri-Council Policy p. 1.5)

**Balancing Harms and Benefits.** This means that the "foreseeable harms should not outweigh anticipated benefits" (Tri-Council Policy, p. 1.6)

**Minimizing Harm.** This involves the duty to avoid, prevent or minimize harm to research subjects. Participants should not be subjected to unnecessary risks of harm.

**Maximizing Benefit.** This involved maximizing the benefit to the study participants and others or society. It includes providing access to the findings of the research.

## **Procedures for Implementing Policy on Ethical Conduct for Research Involving Human participants**

Revised procedures approved by the Senior Executive October 31, 2007

1.0 Any individual(s) wishing to conduct research within the context of, or associated with, Seneca College, whether locally or in other jurisdictions or countries is required to submit to the Chair of the Research Ethics Board the fully completed *Application for Ethics Review* form (attached).

1.1 ALL research conducted in association with Seneca College must be approved in writing by the Seneca Ethics Board prior to beginning any such research.

1.2 The College does not currently engage in any research involving human remains, cadavers, tissues, biological fluids, embryos, fetuses or similar biological elements, or biomedical research.

In the event that research of this nature should be undertaken, the written approval of the Ethics Review Board must be obtained prior to beginning any such research.

1.3 In the event that the research should involve clinical trials, selection of participants shall be made by the most appropriate research design.

1.4 Normally naturalistic observation requires ethics review with the exception if the subjects are seeking public visibility.

Research about events or living individuals involved in the public arena or based exclusively on publicly available information and materials is not required to undergo ethics review, unless the individual is to be contacted directly for interview or access to private documents, in which case ethics review is required to ensure that approved ethics protocols are observed.

1.5 Research related to normal educational program processes and requirements, such as evaluation of student learning, quality assurance and performance reviews, do not require ethics review.

2.0 All applications for approval to conduct research involving human participants must be reviewed by the Research Ethics Board (REB) or in the case of expedited review, by the Chair and one or two members of the REB.

### **3.0 Research Ethics Board (REB)**

3.1 The Research Ethics Board is mandated by the President of the College to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants based on their assessment of the compliance with this Ethics Policy and Tri-Council standards of any research conducted under the auspices of the College. The REB shall have the appropriate administrative and financial independence to enable it to fulfil its mandate.

3.2 A decision of the REB to disallow research on ethical grounds, unless reversed on reconsideration by the REB itself, may only be reversed through the appeals process as stated in paragraph 7 below.

3.3 Initially the College will have only one REB but as research activity increases, additional REB's may be added whose membership will be as stated in paragraph 3.4 will not be specific to any one school or department and whose mandates will be as defined by the research domain and as stated in paragraph 3.1 above.

Once additional REBs are set up, processes will be put in place to ensure that lines of communication are opened in order that each REB is kept aware of the research under review and of the decisions made by the respective REBs.

Should researchers conduct biomedical research at or within the auspices of Seneca College, the REB will have a member knowledgeable in the relevant law.

3.4 The members of the REB will be appointed by the Associate Vice President, Research & Innovation in consultation with relevant college administrative staff, and will consist of a minimum of 5 members per REB, include both men and women, none of whom are administrators, 2 of whom have broad expertise in research, at least one is knowledgeable in ethics and at least one external community member who has no affiliation with the College, selected for their expertise in the research process or in ethics.

- Members will normally serve for three years and may be re-appointed. The term of appointments of REB members will be staggered to ensure continuity and representativeness of the membership as defined above.
- The Chair is elected by the members of the REB and serves for three years.

3.5 The REB will meet face to face at least once per month to review applications received and more frequently (e.g., if the applicants are responding to previous input from the REB) at the call of the Associate Vice President Research & Innovation as needed. For discussions about other than full

reviews, members of the REB may elect to participate in these meetings by teleconference if necessary.

- Research proposals not delegated to expedited review must be reviewed in face-to-face meetings of the REB
- A schedule of the meetings of the REB will be available to all researchers
- Frequent absence of members from regularly scheduled meeting of the REB shall be construed as notice of resignation and the Associate Vice President Research & Innovation will seek an appropriate replacement for that member.
- Agreement among at least 4 members of the REB reflective of the membership as identified in 3.4 above constitutes a quorum in the decision making process.
- A member of the REB with a conflict of interest may not participate in or be present during the discussion and decision related to the research application where the REB member is in conflict of interest.

### 3.6 Decision making process

- REB members will ensure that all applications receive a fair hearing, decisions are made impartially, and the researcher(s) is provided with a reasoned and full explanation of the REB's decision in a written Decision Letter. This includes the reasons for the decisions made and if there were any dissents (in order to facilitate any reconsideration and/or appeal).
- The Chair of the REB will ensure that minutes of each meeting and decisions reached are recorded and all documentation is stored securely at all times and accessible to authorized representatives of the institution, researchers and funding agencies/sponsors.
- The Chair of the REB will submit a written report of the REB's decisions to the Associate Vice President Research & Innovation within one week of the decision.

3.7 The members of the REB will engage in discussion and professional development opportunities related to their role and responsibilities as appropriate.

3.8 Members of the REB and/or the researcher may request informal meetings to discuss and clarify the application prior to the official meeting of the REB on that researcher's application for ethics review.

4.0 No research activities may begin until the applicant receives written approval from the Research Ethics Board.

The Research Ethics Board will take a proportionate approach to ethical review. The greater the possible risk of harm to participants, the more thorough the scrutiny in a full review. Where there is any doubt about the potential risk, a full review will be conducted.

4.1 Full Review: If the applicant elects a full review, or if the Chair of the REB determines that an expedited review is inappropriate, the Chair will call for a review of the application by the full REB. The applicant may be present to discuss or explain the proposed research but may not be present when the REB makes its decision.

Full Review is always the default position.

4.2 Expedited Review: Where there is no foreseeable harm, or only a "minimal risk" to participants, (i.e., where the probable level of risk is reasonably anticipated to be no greater than potential subjects may encounter in everyday life) or if the research has been formally approved (in writing) by a duly constituted REB under the TCPS of another institution (e.g., college or university) the

researcher may apply for expedited review to be conducted by a sub-committee consisting of the Chair and or one or two members of the REB who will make the appropriate decision.

**4.3 Scholarly Review:** The research design of projects that are conducted in partial fulfilment of graduate studies requirements and approved by the faculty supervisor and university, will be deemed to be acceptable unless in the view of the REB, the research poses more than a minimal risk to potential participants, in which case the REB must satisfy itself that the proposed research is capable of answering the research questions posed.

Research conducted by Seneca employees or involving the Seneca community in another jurisdiction or country must be approved by the REB of both Seneca College and the REB (if it exists) at the other jurisdiction. Faculty and staff conducting research in other jurisdictions are expected to meet accepted scholarship standards and the Seneca Integrity in Research and Scholarship Policy.

5.0 The applicant will be notified in writing in a timely manner allowing for due process (e.g., normally within 2 weeks of the review meeting) of any issues that need to be addressed, deny or grant approval to proceed.

The Chair of the REB will submit to the Associate Vice President Research & Innovation for safe keeping, a record of the application received and the decision of the REB.

6.0 In the event the researcher is not satisfied with the decision of the REB, the researcher or the Associate Vice President Research & Innovation may ask the REB to reconsider their decision. If the issues cannot be resolved at that point, the researcher may officially appeal the decision.

## **7.0 Appeals Process**

The decision of the REB may be appealed by the principal investigator(s) through the standing Research Ethics Appeals Committee (REAPC), whose membership consists of:

- minimum of 5 members who are NOT members of the REB; 2 of whom have broad expertise in research, at least one knowledgeable in ethics, and at least one member external to the College (e.g., York University Professor) and none of whom are administrators
- selected for their expertise in the research process and in ethics

## **8.0 Informed Consent**

Upon approval of the REB, the principal investigator must ensure that potential participants are invited to participate in a clear and transparent manner that gains their trust and encourages participation in the study, and invites them to give their informed consent to do so under the following terms and conditions (see templates for Information and Invitation Letter and Consent Form):

- all participants are informed of the nature of the research, and how they will be asked to participate (e.g., the duration of the study, how much time they are asked to devote and how they will be selected). If participant selection is to be based on random selection, the participants must clearly understand how this will be achieved and what this means to them.
- they understand the potential risks and benefits of the research.
- that their participation in the research is entirely voluntary and there is no actual or perceived coercion to participate
- that the participants may withdraw from the study or not answer any questions they do not wish to answer, without explanation or penalty.
- that none of the participants will be identifiable in any dissemination of the findings, or where they may be identifiable, that the participants specifically consent to this.

- only the data of those participants from whom an informed consent is obtained will be included in the study; none of the data of participants who withdraw from the project will be included in the findings.
- all hard and electronic copies of the data will be kept secure, accessible only to the researcher(s), and will be fully destroyed within the identified time period.
- while written evidence of free and informed consent is the norm, in circumstances where the written consent is not appropriate, the REB may accept documentation of verbal consents that are witnessed and confirmed by a neutral third party, or implied consents where the participants indicate their understanding of the research and conditions and indicate their consent by participating directly in the data collection (e.g., online surveys)

Informed consent must be obtained in writing from parents/guardians of individuals deemed to be under age 18 or incompetent to consent.

### **Obtaining the Consent of vulnerable persons**

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

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

For research involving incompetent individuals, the REB shall ensure that, as a 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 subjects' 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 subject in research, so long as the subject remains incompetent.
- d. 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 subject's dissent will preclude his or her participation.
- e. When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

Free and informed consents are normally obtained in writing and kept in a secure file by the researcher(s). Where the research includes an internet based survey, the informed consent may be obtained electronically as part of the actual survey.

9.0 All ongoing research is subject to continuing ethics review which at a minimum consists of an annual report submitted by the principal investigator to the REB chair. Where the REB perceives there to be more than a minimal risk to participants, they may request more frequent reporting consistent with the nature of the research.

10.0 The principal investigator is responsible for notifying the REB immediately if any major changes in the research methodology and procedures are anticipated and explanation of how the rights of human participants will be safeguarded. The research may not continue until approval to do so is again granted by the REB.

The principal investigator is responsible for notifying the REB immediately if any adverse effects are encountered by participants.

11.0 Where the research is supported financially from external sources (e.g., CFI, OIT, Tri-Council granting agencies), the principal investigator is responsible for the approved use of these funds and for meeting all the reporting requirements of the granting agency.

**Signature:**

A handwritten signature in black ink, appearing to read 'Katharine Janzen', with a long horizontal flourish extending to the right.

**Associate Vice President Research & Innovation**

**Date: November 30, 2007**