

Research Ethics Board Policy - Nova Scotia Community College (NSCC)

Purpose of the Policy

In keeping with policies of the Canadian research granting agencies and current practices in research, Nova Scotia Community College (NSCC) has a formalized review process for research projects involving humans. In order to comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*, the NSCC established a Human Research Ethics Board, hereafter referred to as the NSCC REB (or for the purposes of this document, simply as the REB) with a mandate to approve, reject, propose modifications to, or terminate research involving human subjects that is conducted within NSCC or by its staff and students.

The REB and its Policy is aligned with the requirements and guidelines set out by the Tri-Council agencies. This NSCC Policy allows NSCC researchers engaged in scholarly research involving human participants to apply for and conduct research with funding from the national granting agencies: Social Sciences and Humanities Research Council (SSHRC), Natural Sciences and Engineering Research Council (NSERC), and the Canadian Institutes of Health Research (CIHR). The review itself will be based on the principles of ethical interaction, which include the respect for persons (requirement of informed consent by participants), concern for welfare (minimization of risks to participants), and justice (fair and equitable treatment to ensure benefits are realized and that no harm occurs).

With the implementation of this Policy, all research projects and surveys which involve human participants, human remains, human tissue, cadavers, biological fluids and human biological materials (including human embryos, fetuses, fetal tissue, reproductive material and stem cells) for purposes other than quality control (e.g., course evaluation forms) or day-to-day operational practices of the institution must be reviewed by the REB. This applies to funded and unfunded projects, research, and technical projects which involve human participants. It will also apply to external researchers seeking to use NSCC students and/or staff for research purposes. All research that falls under the auspices of this policy must receive REB approval before the research can be started. Excluded from REB review are NSCC practicums as they are training-oriented.

Membership

The REB is appointed by, and reports to, the President of the NSCC. Administrative support and funding for the REB will fall under the auspices of the Office of Applied Research.

There is only one REB at NSCC and it will consist of at least six (6) members, including both men and women, appointed by the NSCC President and will be comprised of:

- The Chair;
- One (1) member knowledgeable in law (but not the institutional counsel);
- One (1) member knowledgeable in ethics;
- One (1) community member who has no affiliation with NSCC but lives within the province of Nova Scotia;
- Two (2) research or faculty members who have a broad expertise in research covered by the REB;
- Other members on an as needed basis (ex officio, and without vote) for advice on specific proposals.

Term of Membership

College members shall be appointed for an initial three-year term, with re-appointment at the discretion of the President.

Community members shall be appointed for a period of three years, and may be re-appointed upon mutual agreement with the President.

Every effort shall be made to stagger membership times, so that there shall at all times be a balance of newer and longer-serving members.

Research Requiring REB Approval

NSCC is accountable for all research undertaken at its Institution, where research is defined in the Tri-council Policy Statement as “a systemic investigation to establish facts, principles or generalized knowledge”. NSCC, through this policy, delegates the ethical review of research involving humans to the REB and will support and respect the REB’s operations and decisions. Under this mandate, the REB can approve, reject, propose modifications to or terminate any proposed or ongoing research involving humans which is being conducted within NSCC or by its faculty, staff and students.

The following is a sample of projects which might typically arise at NSCC that would require REB review: questionnaires, surveys or interviews of individuals where the human being is the participant of the investigation and personal opinions and practices are documented. This is in contrast to when the participant serves as the source of information about a business, a company, a community group, etc. without putting themselves into a situation where their risk is above minimal risk. Minimal risk is defined as an occurrence where possible harms (such as physical, psychological, social, and economic harms) which may occur from participation in the research are within the range encountered by the participant in everyday life.

NSCC researchers conducting research in other jurisdictions or countries must obtain ethical approval from NSCC's REB and also from the REB where the research will be conducted.

REB approval is normally required for naturalistic observation of humans. However, this requirement may be waived if the researcher is conducting an observational study where participants are in a public arena and the participants intend for their comments and conduct to attract public visibility.

Research Excluded from REB Approval

Some projects are considered exempt from this process. Research that is conducted solely for the purpose of internal institutional evaluation or quality assurance purposes is not subject to REB review although members of the NSCC community should be aware of possible ethical considerations of their actions and, specifically, of their interactions with humans. Even where ethical review may not be required, it is good practice to clearly communicate the purpose of a project and the intended use and release of the results. If there are any questions about the need for a specific survey or project to undergo ethics review, they should be directed to the Chair of the REB. Research of this nature is also governed by NSCC policies with respect to privacy of student and employee information and appropriate use of institutional data. Research based on information that is publicly and legally accessible does not require REB review. For greater clarity, the following is a non-exclusive list of research that would not normally be subject to review:

- questionnaires, surveys or interviews conducted by NSCC of present and/or former students, employees and prospective employers for purposes of modifying the curriculum, course evaluations, program or service needs assessment or evaluation, student, graduate or employee opinions, satisfaction and outcomes.
- questionnaires, surveys or interviews conducted by NSCC students as a project or assignment as part of any course or program in which the student is enrolled. Faculty are responsible for ensuring that students undertaking research of this nature are aware of NSCC's policies with respect to research ethics, privacy of personal records and use of institutional data, and that the work is carried out according to the principles used by the REB. In cases where doubt exists, all such projects should be submitted to the REB for approval. Normally these will be dealt with by the expedited review process.

NSCC researchers conducting multi-jurisdictional research involving humans must obtain approval from the NSCC REB as well as from the REB in the jurisdiction in which the research will be conducted. The NSCC REB will provide a proportionate review of the project as it would for any submission and will require that the researcher submit the details of the host site where the research will be conducted. This will include the contact information for the relevant

external REB or, in the absence of an REB, the rules governing human research and ethical review in the country in which the research will be conducted. If the research is to be conducted in a country outside Canada where equivalent ethical and procedural safeguards are non-existent, the NSCC REB must be satisfied that the study will be conducted according to the guiding principles set out in this policy.

Responsibilities

The NSCC President:

- has the ultimate responsibility to ensure that NSCC complies with the Tri-Council Policy Statement (TCPS);
- appoints members to the REB;
- ensures that the necessary financial resources are available for the REB to execute its responsibilities .

The REB Chair:

- calls and chairs regular meetings of the REB and other meetings as required;
- maintains and coordinates communication with REB members and with the Office of Applied Research;
- communicates REB decisions to the researcher;
- ensures that there is consistency in the decisions taken by the REB;
- participates in the expedited review process;
- recommends experts to the REB as needed to supply expertise in specific areas;
- initiates information and education sessions for the campus community;
- ensures official copies of REB minutes and decisions are sent to the Office of Applied Research for filing purposes.

The Office of Applied Research at NSCC is responsible for:

- disseminating the schedule of REB meetings to campuses (such notices shall normally be issued in September and January);
- receiving applications from faculty, researchers and students and forwarding them to the Chair;
- holding funds awarded to NSCC researchers until the required REB approval has been given;
- ensuring that the filing of REB minutes and documents is up-to-date and making these minutes available to representatives of the institution, researchers, and funding agencies;
- communicating with external organizations (e.g., SSHRC, NSERC, CIHR);
- providing recording secretary services at all Board meetings;
- serving as a communication link between senior management and the internal college community;

- recommending/advising the REB on policy and procedural matters that impact REB operation and decision making;
- arranging professional development sessions for the REB.

The Researcher is responsible for:

- 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 participants for which the research is planned. The researcher shall carefully monitor and assure the validity of the research submitted to the REB.
- obtaining additional approval from NSCC's Institutional Research Office if the research involves NSCC students, staff and/or faculty. This process is separate from the responsibilities of the Research Ethics Board. The purpose of the Institutional Research Office's review of the project is to ensure that it meets NSCC's internal guidelines and policies.
- becoming familiar with applicable ethical guidelines and abiding by these guidelines and this policy;
- deciding whether their proposed research requires ethics review. If there is any uncertainty on this point, the researcher should consult the Chair of the REB for advice and decision.
- submitting a fully completed application to the REB to request ethical approval;
- ensuring REB approval is received in writing before starting the research;
- abiding by all decisions and requests of the REB;
- obtaining free and informed consent from all participants as outlined in this policy;
- maintaining confidentiality of data as required by the REB and regulatory laws;
- promptly reporting to the Chair of the REB any injuries to participants, any unanticipated problems which involve risks or unusual costs to the participants, or other adverse events resulting from the research;
- promptly reporting to the Chair of the REB any proposed changes in the research which would result in a significantly different involvement of participants and waiting for REB approval before proceeding with the changes;
- promptly reporting to the Chair of the REB any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by the REB.

REB Meetings

The REB will schedule, as much as possible, regular monthly review meetings and the Chair will communicate this schedule semi-annually to the Office of Applied Research, so that the schedule can, in turn, be communicated to the

College community. Every effort will be made to move the meetings of the Board around the various campuses of the NSCC.

The REB meetings will normally occur in a face-to-face format with all members present. Recognizing that it may sometimes be difficult for NSCC to have a full complement of "alternates" in the various membership categories (e.g., ethicist) laid out in the Guidelines, the Chair will:

- ensure the full REB will be present for all meetings where a proposal will be reviewed;
- when, due to **sudden, unexpected and extenuating circumstances**, the full REB cannot meet, a quorum of four (4) members will be sufficient to allow a review meeting to proceed. Where a review meeting is conducted in the absence of critical input of one (1) or more members, then the Chair **must** consult with those members. If, and only if, the member(s) are of like mind with the rest of the REB will the Chair consider a decision final and communicate same. If any concern or disagreement is evident, then the decision must be delayed until some future time when all members of the REB are in attendance.

Review of Proposals

The REB will use both Expedited and Full Reviews as allowed in the Tri-Council Policy Statement. Regardless of the method of review, full or expedited, the REB continues to be responsible for the ethics of all research involving humans carried out within the jurisdiction of NSCC.

Full Reviews will be used:

- to evaluate proposals where the level of risk is above minimal risk;
- to review previously approved proposals where a change to the research protocol is to be implemented.

Decisions on full reviews will only be adopted if the members in attendance possess the range of background and expertise stipulated in the "Membership" section of this policy.

Expedited Reviews may be used:

- to assess proposals involving only minimal risk;
- to act on behalf of the REB to approve minor changes made by a researcher at the request of the REB;
- to review annual renewals of approved projects in which there has been no change in the ongoing research;
- to monitor on-going research which involves minimal risk;
- to ratify undergraduate and technical course and research proposals that have been recommended by a departmental group which acts as a subcommittee of the REB;
- to review proposals which have already been approved by another institution's REB.

Expedited reviews will be conducted by the Chair and another regular member of the REB who has expertise in the area of the application. For these reviews, face-to-face meetings will be encouraged but not considered mandatory. In order to ensure that the REB maintains surveillance over decisions being made for them, the outcome of expedited reviews will be communicated by the Chair to all members, with a request to provide 24-hour turnaround response on the proposed decision. In addition, any item that is granted an expedited review will be brought forward as an agenda item at the next full meeting of the REB to ensure that all members receive a full report on the expedited review. The REB reserves the right to obtain further clarification from the researcher during the period of the research.

Principles of Ethical Review

The following principles will be followed:

- All decisions will be reached by consensus. If approval is not readily forthcoming, then the REB must arrive, by consensus, at one of two possible decisions:
 1. recommended modifications that would make the project acceptable to all REB members, or
 2. rejection of the proposal.
- All proposals will be subjected to an assessment of individual and institutional risks and potential benefits. The REB will conduct a proportionate review approach where research involving risk of harm to participants will be subject to greater scrutiny than research deemed to be of minimal risk. Minimal risk is defined as an occurrence where the possible risks involved in the research will not result in any greater harm to participants than those they may encounter in the normal course of their everyday lives.
- Where the risk is determined by the REB to be above minimal risk levels, the REB will have the prerogative and responsibility to confirm the proposed research meets scholarly standards. In the event there are no results of a formal peer review available, the Chair will request the applicant to supply the names of three (3) reviewers the applicant would be willing to have review the proposal. Some or all of these reviewers will be asked to comment on the scholarly content and standards of the proposed research. Research deemed to have above minimal risk must meet scholarly standards before it will be considered further in an ethical review.
- Any REB member must disclose any potential conflict of interest in the research being considered. If personal conflicts exist, the REB member must not be present for discussions or decisions related to the application.

Free and Informed Consent

Researchers must obtain free and informed consent from participants, or authorized third parties, prior to their inclusion in the research and participants should be made aware that they have the right to withdraw their consent at any time during the course of their involvement. Participant consent must be voluntary; given without any due influence, manipulation or coercion. Consent must be documented which in most cases is in the form of a signed consent form by the participant. However, if for cultural or other valid reasons a written consent is not possible to obtain, then the researcher must document the procedures to be used to obtain free and informed consent.

Free and informed consent must be obtained in projects even if the research involves random assignment of the participant to a particular element of the study. This may occur in clinical trials where the participants and the researcher are blinded to the selection process prior to the start of the study. In these cases, the researcher will ensure that the consent form explains the process of how the participant will be chosen for a particular group within the study and outlines the benefits and/or risks associated with each possible assignment.

Exceptions to Free and Informed Consent

There are instances where the REB may alter the requirement for free and informed consent provided that the following, as outlined in the TCPS, Article 2.1 (c), exists:

- The research involves no more than minimal risk to the participants;
- The alteration or waiver is unlikely to adversely affect the welfare of the participants;
- The research could not practically be carried out without the waiver or alteration;
- Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
- The waived or altered consent does not involve a therapeutic intervention.

Full Disclosure to Participants

Full disclosure on the nature and purpose of the study must be ensured in order for the participant to make an informed decision on participation and would generally include:

- a clear, understandable description of the purpose of the study and an invitation to participate;
- the researcher(s) names and any funders or sponsors;
- how the study will be conducted, the time commitment and other responsibilities of the participant;
- anticipated risks and benefits to the participant;

- assurance that the participants will be able to withdraw at any time, including their data where possible, without prejudice to pre-existing entitlements and that they will be given continuing and meaningful opportunities for deciding whether or not to participate;
- information on how the results of the study will be disseminated, including any potential commercialization outcomes;
- how the collected information will be protected; this includes information on who will have access to the data, how it will be stored, how it will be used and when it may be disclosed;
- contact information for any questions regarding the methodology or academic aspects of the research;
- contact information should the participant have any concerns regarding ethical issues of the research;
- information on any known expenses, any reimbursement plans, any incentives or other compensation issues.

Participant Competence

If potential participants are not legally competent to make an informed decision on consent, a third party, who possesses no conflict of interest with regards to the research and are not part of the research team, may be appointed to make an informed decision on behalf of the participant. This delegation of consent will be allowed if the research question can only be addressed by using the individuals from the identified group and if the research does not expose the participant to more than minimal risk without the potential for direct benefit to them.

For research involving 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 participants' best interests will be protected.
- The authorized third party will not be the researcher or any other member of the research team.
- For as long as the participant remains incompetent, the continued free and informed consent of an appropriately authorized third party will be required in order for a legally incompetent participant to continue participation in the research.
- 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 as a condition of continuing participation.

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.

Research in Emergency Health Situations

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

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

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.

Submission of Proposals for Review

The Research Ethics Board Application Procedure form outlines in detail the required information to be included in submissions to the REB. Researchers are responsible for ensuring that applications are complete before they will be evaluated by the REB and must include and/or address:

- name of the primary applicant, contact information (email address), context of the research proposal (faculty research, graduate student research, undergraduate, technical project or course work);
- the project description, including purpose, methodology, societal value;
- survey, questionnaire form or other data collection form;
- methods used to ensure consent of the participant and a copy of the consent form;
- real, and potential, harms and benefits to the participants;
- record of any verbal communication which will take place with the participants;

- the use(s), retention, disclosure of the data as well as the means to ensure confidentiality;
- the names of any other institutional REB's which will be reviewing the proposal;
- an estimation by the researcher of the magnitude of risk (minimal risk, exceeds minimal risk).

The submission must also include provisions for continuing ethics review. It is the responsibility of the applicant to make provisions that are based on the proportional risk levels of the project. Identification of multi-centered research and the sites involved in the research should be disclosed to the REB to allow possible coordination of review with the other REBs. Disclosure on items deemed core elements of the multi-centered research may facilitate the ethics review process.

Incomplete proposals will be returned by the Chair to the applicant with a resulting delay in REB consideration. All researchers will submit their proposals to the Office of Applied Research. All proposals must be received at least seven (7) working days before the REB meeting in which they are to be reviewed. Meeting this deadline does not guarantee the review of the proposal at the next REB meeting; however, the REB is committed to efficiently reviewing proposals.

All proposals submitted must be in electronic form (Word preferred). Applicants may, on occasion, be requested to also submit a hard copy of supporting documentation or materials.

Decisions and Communication of Decisions

All decisions shall be made by consensus.

The Chair will be responsible for communicating the decision on all proposals to the originator and to the Office of Applied Research. For NSCC student proposals, the decision will be sent to the Course Instructor/Supervisor, the Academic Chair, and the student. This communication will be sent no later than two (2) working days after the REB has reached a consensus. In isolated situations, the Chair may ask the applicant(s) to provide additional information before making a decision.

Where a negative decision, as opposed to a modification request, is being considered by the REB, the Chair will provide the researcher/s with the complete list of concerns and allow them to respond to these items before the REB decision is finalized.

The Chair will also ensure a detailed record of the decision is sent to the Office of Applied Research to be retained on file for five (5) years.

Documentation

All documents, minutes and decisions shall be kept in the Office of Applied Research where they will be accessible to authorized representatives of NSCC, researchers and funding agencies. Wherever possible, all documentation shall be in computerized form. Minutes shall include a summary of the discussion that takes place around each application and record any problematic issues and the reasons for them. Each file should contain an excerpt from the minutes pertaining to that application.

Reconsideration and Appeals

Where the applicant does not agree with the decision of the REB, she/he has the right to ask the Chair to see the minutes of the meeting where that proposal was discussed. The researcher can also request of the Chair that the REB reconsider the case. By invitation, the researcher may appear in person to discuss the research with the REB. The researcher will withdraw before the REB makes a ruling on the Reconsideration. Every effort will be made to resolve the disagreement through discussions, consultations and/or external advice from experts in the area of the research.

Should the applicant still express dissatisfaction, an appeal of the decision can be requested and an external review of the application will be arranged. Such a review will be made under standing arrangement with the College of the North Atlantic, and the results of this external review shall be final. Researchers must justify on what grounds they request an appeal and indicate the breaches to the research ethics process or the elements of the REB decision that are not supported by this Policy.

The College of the North Atlantic REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. Through this appeal process, the College of the North Atlantic REB is granted the authority to approve, reject or request modifications to negative decisions made by the NSCC REB. Outcomes of the appeal process will be communicated in writing to researchers in print or by electronic means.

Continuing Review of Research

Continuing ethical review will be conducted on all research whether of minimal or above minimal risk. The degree of the ongoing review will be based on the proportionate level of risk. The researcher shall provide the REB with proposed suggestions to allow for continuing review with a minimum requirement of providing an annual update on the status of the research and an end of study report. The REB will determine the requirements to ensure ongoing review and will, at the least, review the annual update to ensure the project continues to meet their approval.

Education

The REB has a two-fold responsibility toward the College; in addition to its review mandate, the REB shall also be responsible for educating faculty, students and staff with respect to the area of human research ethics, the Policy and the Review Process. This need for on-going education and communication also includes the self-education of the REB members.

Annual Report

There shall be an annual report of the activities of the REB submitted to the NSCC President each fall. The report shall contain the statistics of applications, and comment/recommend upon any matters arising from meetings.

Modifications to this Policy

The REB has the right, within the Tri-Council Policy Statement, to recommend changes to this Policy from time to time. Any recommended changes must be approved unanimously by all of the members of the REB. The requested changes will be sent to the President of NSCC for final approval by the Board of Governors before they are implemented.