POLICY

Research Ethics Board Policy	Board of Governors

PURPOSE

The purpose of this policy is to ensure that all research projects and surveys involving 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 or day-to-day operational practices of the institution, are reviewed and approved by the Research Ethics Board (REB). The REB and this policy comply with the with the requirements of the Panel on Research Ethics (PRE), under the Secretariat on Responsible Conduct of Research, to ensure that all research is conducted according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS2).

STATEMENT OF POLICY/SCOPE

This policy applies to all staff and students and to external researchers seeking to use NSCC students and/or staff for research purposes. It applies to funded and unfunded projects, research, and technical projects which involve human participants or human-related tissue and materials. All research that falls under the auspices of this policy must receive REB approval before the research can begin. Under this mandate, the REB can approve, reject, propose modifications to or terminate any proposed or ongoing research. Typical projects that require REB approval at NSCC involve questionnaires, surveys or interviews of individuals where the human being is the participant of the investigation and personal opinions and practices are documented. 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.

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 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 on 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 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 information and use of institutional data, and that the work is carried out according to ethical standards of the TCPS2. In cases where doubt exists, all such projects should be submitted to the REB for review.

REB review is not required for research that uses publicly available data, observes people in public places where there is no expectation of privacy, or for research that relies exclusively on secondary, anonymous data that can, in no way, be linked to identifiable information.

DEFINITIONS

Research Ethics Board (REB) conducts reviews of research involving human participants and has a mandate to approve, reject, propose modifications to, or terminate research that is conducted by or on staff and students.

Panel on Research Ethics (PRE) is responsible for addressing the evolving needs of the three research agencies (Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council, and the Canadian Institutes of Health Research) in promoting the ethics of research involving humans. It provides guidance consistent with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2nd edition (TCPS2).

Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2) includes the guidelines for conducting research involving humans and is the basis of this policy http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

POLICY

The REB will review all applications in accordance with ethical guidelines governing research involving human participants as articulated in the TCPS2. REB review is 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).

The REB shall be responsible for educating faculty, students, and staff with respect to the area of human research ethics. The need for on-going education and communication also includes professional development for the REB members. Anyone conducting research on humans and the REB members should complete the on-line TCPS2 Tutorial, “Course on Research Ethics” (CORE).

The REB will use a proportionate approach in conducting its reviews based on their perceived level of risk to the participants; either a Full review or a Delegated review will be considered. A Full Review, involving a full quorum of REB members, will be used to evaluate all proposals unless the research is deemed to be of minimal risk to the participants. Minimal risk is defined as research where the possible harms to the participant are no greater than those they would encounter in their everyday life. Delegated reviews may be used in the following circumstances:

- to assess proposals involving only minimal risk;
- to approve minor changes to the research protocol;
- to review annual renewals of approved projects where there is no substantive change to the 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.

Full reviews will be conducted by a quorum of REB members in a face-to-face meeting and all decisions will be reached by consensus.

Delegated reviews will be conducted by the Chair and at least one other member of the REB who has expertise in the area of the application. In order to ensure that the REB maintains surveillance over decisions being made for them, the outcome of delegated reviews 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 delegated review. Monitoring and review of ongoing research will be continuing and the REB reserves the right to obtain further clarification from the researcher during the period of the research.

In all cases, the REB will have the prerogative and responsibility to confirm the proposed research meets scholarly standards.

Continuing ethical review will be conducted and 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.

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.

Upon completion of the REB review, the outcome will be classified as: approved; approved with suggestions; not approved unless specified conditions are met; or not approved. The Chair will be responsible for communicating, in writing, the decision on all applications. When an application is approved with suggestions or not approved, the applicant will be provided with a list of concerns to allow them to address the issues before an REB decision if finalized. The researcher's replies, depending on the circumstances of the review, will be considered by the Chair to ensure they are acceptable except in the case where the application was originally not approved. In this case, the researcher's amendments must be considered by the full board. REB approvals are granted for a maximum of one year and further approval will be dependent upon the REB's receipt and review of an updated annual report and request for renewal of ethics approval.

If the REB does not approve the application, every effort will be made to resolve any disagreement with the researcher through discussions, consultations, and/or external advice from experts in the area of the research. In the event the REB issues a final "not approved" outcome, the researcher has the right to ask the Chair for 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.

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 provide justification on the grounds of the appeal and indicate the breaches to the research ethics process. 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 NSCC's REB. Outcomes of the appeal process will be communicated in writing to researchers.

DOCUMENTATION:

All documents, Minutes and decisions shall be retained on file by the Research Ethics Coordinator where they will be accessible to authorized representatives of NSCC, researchers, and funding agencies. 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.

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. Participant consent must be ongoing and voluntary; given without any undue 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.

There are exceptions to free and informed consent when the research question could not practically be carried out without the waiver or alteration. When possible and appropriate, the participants will be provided with additional pertinent information or a debrief after participation.

To ensure full disclosure on the nature and purpose of the study and so the participant can make an informed decision on participation, the Consent form must include:

- a description of the purpose of the study and an invitation to participate that is written at an understandable level for the intended participant cohort;

- 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 withdrawing 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;
- researcher contact information for any questions regarding the methodology or academic aspects of the research;
- REB contact information should the participant have any concerns regarding ethical issues of the research; and
- a disclosure of any known expenses, any reimbursement plans, any incentives or other compensation matters.

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 individuals incompetent to give their consent, 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; and
- 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. 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:

Applications to the REB must be made using the "Application for Ethics Review of Research Involving Humans". This application outlines 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 all the following items:

- name of the primary applicant, contact information (email address);
- the project summary, including purpose, methodology, societal value;
- planned dates for conducting the research;
- survey or questionnaire or other data collection form;
- the Consent form or an explanation of why there is no Consent form;
- real and potential harms and benefits to the participants;
- record of any verbal communication which will take place with the participants;
- recruitment strategy and any related documents, such as advertisements, letters of invitation, and marketing material;
- the use(s), protection, retention, and storage of the data;
- information on how confidentiality of the participants will be maintained;
- the names of any other institutional REB's which will be reviewing the proposal; and
- an estimation by the researcher of the magnitude of 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.

All researchers will submit their applications to the Chair and/or Research Ethics Coordinator at reb@nscc.ca and those that are incomplete will be returned. Proposals must be received at least seven 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.

REB MEMBERSHIP:

The REB must be comprised of at least six (6) members to form a quorum, including both men and women, filling the following positions:

- Chair;
- One (1) member knowledgeable in law (but not 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 may be asked to join on an as-needed basis (ex officio, and without vote) for advice on specific applications.

The REB Chair is appointed by and reports to the President of NSCC. The initial term of appointment is for three years and reappointment for additional terms is at the discretion of the President.

Other REB members are selected and recommended by the REB Chair and submitted to the President for final approval. The term of appointment may be for up to three years with re-appointment at the mutual agreement of the Chair and NSCC President. Every effort shall be made to stagger membership end dates so there will at all times be a balance of newer and longer-serving members.

The costs associated with coordination of the REB and other associated costs fall under the auspices of the Applied Research Office.

RESPONSIBILITIES:

The NSCC President:

- has the ultimate responsibility to ensure that NSCC meets the obligations and responsibilities outlined in the “Agreement on the Administration of Agency Grants and Awards by Research Institutions” and the “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
- ensures necessary financial resources are available for the REB to execute its responsibilities;
- appoints the Chair of the REB;
- with recommendation from the Chair, approves other members to the REB.

The REB Chair:

- calls and chairs regular meetings of the REB and other meetings as required;
- maintains and coordinates communication with REB members and REB Coordinator;
- communicates REB decisions to the researcher;

- ensures that there is consistency in the decisions taken by the REB;
- participates in the delegated review process;
- recommends experts to the REB as needed to supply expertise in specific areas;
- initiates information and education sessions for the campus community;
- screens REB members and recommends appointments to the President;
- in extenuating circumstances, appoints a Vice-Chair from the REB members to act in the absence of the Chair;
- ensures official copies of REB Minutes and decisions are sent to the REB Coordinator in the Applied Research Office.

The REB Coordinator, Applied Research Office:

- receive and review REB applications for completeness before sending to the Chair;
- distribute applications to the members;
- compile and send the REB members' comments to the applicant;
- hold funds awarded to NSCC researchers until the required REB approval has been given;
- ensure 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;
- communicate with external organizations (e.g., CAREB, SSHRC, NSERC, CIHR);
- record proceedings at all Board meetings and writing the Minutes;
- communicate REB activities to senior management and the internal college community;
- advise the REB on policy and procedural matters that impact REB operation and decision making, particularly providing interpretations on the TCPS2;
- assist the Chair with professional development sessions for the REB;
- distribute meeting materials and organizing meeting logistics.

The Researcher:

- ensure that the research being conducted is scientifically valid and/or appropriate in a scholarly sense, and that the benefits to knowledge resulting 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;
- obtain additional approval and assistance 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 REB and involves informing the Deans of the intended research to best assist the researcher with accessing their cohort;
- become familiar with applicable ethical guidelines and abiding by these guidelines and this policy - it is advisable that the TCPS2 on-line CORE Tutorial be completed and the certificate of completion be submitted with the REB application;
- assess 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 comply with the Chair's decision;
- submit a completed application to the REB to request ethical approval;
- obtain REB approval in writing before starting the research;
- abide by all decisions and requests of the REB;
- obtain free and informed consent from all participants as outlined in this policy;
- maintain confidentiality of data as required by the REB and regulatory laws;

- promptly report 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 report to the Chair of the REB any proposed changes to the research plan or participant involvement and waiting for REB approval before proceeding with the changes;
- promptly report 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 regular monthly review meetings and the Chair will communicate this schedule to the Applied Research Office in advance of meetings. When applications require a Full Review, the Chair will ensure there is a quorum. If a member required for quorum misses a Full Review meeting the Chair must consult with the absent member to determine their evaluation of the proposal. If any concern or disagreement is evident, then the decision must be delayed until the next meeting when a quorum is convened. Only then will the Chair communicate the REB's final decision.

POLICY SUPPORTS

Related Policies:
Research Integrity Policy