Dalhousie Research Ethics Boards

Guidance for Submitting an Application for Research Ethics Review
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Section 1. ADMINISTRATIVE INFORMATION

Only English language documents can be reviewed by the Research Ethics Boards. Please submit all documents in English.

Determining which Research Ethics Board (REB) to submit to: Dalhousie University has two Research Ethics Boards and the assignment of which Board will review a particular project is done according to the subject matter of the research.

Health Sciences REB – reviews research dealing with medical, dental or health and mental health related topics;
Social Sciences and Humanities REB – reviews research dealing with social, behavioural and cultural research in non-health care contexts

Researchers are encouraged to indicate the Board to which they believe their submission should be directed, however the final determination of which Board will review which research rests with the director and/or Board chairs.

1.1 Dalhousie Researcher
This is the researcher affiliated with Dalhousie University who will lead the ethical conduct of the research. Often, this is the principal investigator, or local lead investigator.

Students may be considered to be the lead researcher for their thesis research projects. However, students should only be the named lead researcher on a research ethics file when it is foreseeable that they will complete the full scope of the proposed research during their academic program. In cases where the research may extend past the term of any single student's involvement, the research ethics submission should be made by the faculty supervisor, with student(s) named as other involved study personnel (that can evolve over time). If the group or lab is doing the research rather than the individual student, the supervising faculty member should be the lead researcher on the research ethics submission responsible for the ethical conduct of the research.

In the event that a student is named as the lead researcher, and that student does not complete the full scope of the research by program completion, the supervising faculty member may, normally with the student researcher's written agreement, take over as lead researcher for the project. Researchers are responsible for considering the scholarly integrity issues related to such a change, such as stewardship of data.

This section also asks for current contact information for the lead researcher. Most communication between the Boards and researchers is by email, so it is important to keep this information up-to-date with the Research Ethics office. The email address used for communication must be the official University email address.

The study start and end dates should indicate when you plan to begin and end the parts of your research that involves human participants (or data).

1.2 Student submissions
Complete this section if the lead researcher is a student. Identify your degree program (for example, BSc (Psychology), MD, MA (Health Promotion), PhD (Interdisciplinary)) and provide the name and contact information for the Dalhousie supervisor of the student research. When a supervisor is not affiliated with Dalhousie University, a Dalhousie University administrative supervisor must also be named in the submission. Supervisors will be copied on communication between the Boards and the lead student researcher. The responsibilities of supervisors (and of academic units) are described in the Dalhousie University Policy on Ethical Conduct of Research Involving Humans; Research Ethics has also developed a document that describes the role of the supervisor in research ethics (available on the Resources section of the Research Ethics website).

1.3 Undergraduate (minimal risk) thesis research
Undergraduate students conducting minimal risk thesis research should initially submit their application for unit-level review (to obtain department, school or faculty research ethics approval) prior to submission to the university's Research Ethics Board. Submissions that have received unit-level approval (indicated on the front page of the application form) are eligible for a streamlined review by the Research Ethics Board. The exceptions are research that is more than minimal risk, or where unit-level review is not available, in which case the research ethics application may be submitted directly to the Research Ethics Board.

Course-based (non-thesis) minimal risk research is eligible for unit-level review and approval in those Schools, Departments and Faculties that provide such review; further approval by the University-level research ethics boards is not required.

Minimal risk research is defined in the TCPS as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” (TCPS Chapter 2-B). When in doubt about whether or not research may be considered minimal risk, please consult with Research Ethics.

1.4 Other reviews
Other ethics reviews. Some research projects require ethics approvals at other institutions (other universities, hospitals, colleges, research centres, school boards, etc.) or by other ethics bodies (such as Mi’kmaw Ethics Watch) in addition to Dalhousie University. Complete this section to describe to the REB any other ethics review required for the project and the status of this review (approved, submitted, to be submitted, for example). Information about when a project may need multiple REB approvals can be found in the TCPS Chapter 8 (Multi-jurisdictional Research). It is the researcher’s responsibility to ensure that all necessary approvals are in place before the conduct of research involving humans.

Funding. If the research project is funded, please describe the funding agency and award number. If not, please leave this blank.

If the research project is contingent on funding that has not yet been secured, the REB will not review the ethics application until funding has been committed to the project.

Peer review. If the project has been peer reviewed, please describe this review to the Board in this section.

Contact person. If there is a contact person that the lead researcher would like to have included in
communication between the Board and the lead researcher, please indicate this here. If not, please leave this blank.

1.5 Attestations
The lead researcher must indicate agreement with the attestation regarding the ethical conduct of the research.

Supervisor attestation. As part of the review process, the Board must ascertain whether there is scholarly merit, as research that will not yield trustworthy results in unethical. For this reason, it is important that the student’s ethics proposal be carefully reviewed and approved by the student’s supervisor prior to submission. A well-conceived and carefully presented research project will pass through the ethics review process more quickly than one that has not received adequate input from the student’s supervisor.

The supervisor must attest that s/he has personally reviewed the ethics application prior to its submission and that the scientific/scholarly methods of the research project are sound and appropriate. The supervisor commits to ensuring that the research is conducted following the principles of the Tri Council Policy Statement Ethical Conduct for Research Involving Humans and that the research will be undertaken and supervised as per the University policy, including the Policy on the Ethical Conduct of Research Involving Humans.

All learners, including residents, post-doctoral fellows, undergraduate and graduate students require a supervisor for research.

If the lead researcher and/or student supervisor has completed the TCPS Course on Research Ethics (CORE) online tutorial, please so indicate. The online tutorial may be found through the Research Ethics homepage or at http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/. Completion of the tutorial is strongly encouraged.

Section 2. PROJECT DESCRIPTION

2.1 Lay Summary

2.1.1 In lay language (plain language suitable for educated non-experts in the field), briefly describe the rationale, purpose, study population and methods. This section is meant to orient Board members to the study and to explain the context for undertaking it. It should include references to the literature to substantiate the researcher’s description of why it is necessary to undertake the research. The science of a study – including the study justification – becomes an ethical concern if there is not sufficient reason for doing the research, or the study is inadequately designed to produce valid results. It is unethical to subject participants to any procedures likely to produce dubious results, even if it will simply waste their time.

Mention what new knowledge is anticipated and whether this is a pilot project or fully developed study. A fully developed study is one that is intended to be a stand-alone piece of work whereas a pilot study is intended to test the feasibility of a methodology through data collection and analysis, or is a preliminary investigation intended as the basis for a larger work.

The Tri Council Policy Statement requires that human participant research projects that are defined as “pilot studies” undergo ethics review (TCPS 6.11). Background work to inform the study, where data is
not formally collected, is not subject to review (e.g., talking with experts or gatekeepers, feedback on an instrument, etc). Pilot testing a research design, recruitment and data collection are activities that require ethical review. Pilot study results may be analyzed, may be published, and may inform future work.

Examples of preliminary work that would not require ethical review include:

i. Researchers using a piece of safety-approved test equipment on themselves to work out methodological details for later use in designing a project

ii. A student and supervisor using a piece of safety-approved testing equipment to make measurements as a student training exercise, in preparation for future work. Normally this would involve repeated measurements on the same individual. Data would only be examined to determine the success of the training. Safety issues would be the responsibility of the supervisor.

iii. A researcher asks a group of friends or colleagues to complete a questionnaire to determine the length of time it takes to do so (no data is retained).

When in doubt about whether or not a particular activity constitutes a pilot study requiring ethics review, consult with Research Ethics.

2.1.2 When later phases of the work are contingent on the interpretation or output of earlier stages, it may be appropriate to request a “phased review”. Phased reviews involve an initial presentation of the overall research plan, including the rationale and study design and plans for data analysis. At the time of ethics submission, however, it may only be possible to submit research instruments (e.g., questionnaires, interview guides) that relate to the initial phase of work. The researcher should clearly indicate what is being submitted for initial review and approval and what will be submitted later for review and approval of later phases. Phased reviews are not appropriate for studies that can be presented in their entirety at the outset, even if there are several sequential steps of data collection.

In conducting an ethics review, the Board must have the opportunity to examine the instruments that the researcher plans to use in order to have a clear understanding of the kinds of information that are sought, and the ethical issues that might relate to this information. This review must take place prior to the instruments being used. However, some study designs make it impossible to include all the research instruments in advance of the project commencing. Some research projects involve a number of steps that build on each other for the express purpose of developing and implementing the research instruments over the course of the study. For example, researchers might wish to hold a focus group with community members, with the intent of collecting the information that guide the development of a questionnaire that will be used at a later stage of the study.

In order to accommodate these sorts of projects, the Board has developed a process called “phased review”. This process involves the initial review by the Board of all aspects of the project that can be presented at the outset of the project (as outlined in these guidelines), and a plan for submission and review of later components. The following describes how such a review would proceed.

STEP 1 - initial review
- The researcher prepares a submission presenting the rationale and scholarly context for the entire study, including a description of the research plan in phases (i.e., Phase 1, Phase 2, etc.)
- The submission would indicate which phase is being submitted for review and approval at the
time of submission. NOTE: The Board can only review and approve that portion of the study for which all necessary documentation is available (i.e., recruitment instruments, consent forms, research instruments). These must be included in the submission.

- The submission should also indicate how the researcher intends to submit future phases for review.

STEP 2 - future review

- At the completion of that portion of the research for which approval has been received, and prior to advancing to the next phase, the researcher should submit the next phase(s) of the study for review (as a new submission to the Board).
- This submission should include a description of the progress of the earlier phase(s), a description of the details of methodology for the next phase(s), any instruments or consent forms to be used in the next phase(s).

Phased reviews are only conducted when the need to do so is dictated by contingencies within the study design. Piece-meal submission of a project that could be submitted as a whole will not be considered. More commonly, researchers may submit an application that has multiple steps, seeking approval for the entire project, but may note that refinement of the instruments for later stages will occur after early steps are complete. The project may be approved with draft instruments, though the researcher is responsible for submitting the refined instrumentation as an amendment request.

2.2 Research Question

Some studies are intended to test hypotheses or to address specific research objectives, while others are more exploratory or inductive, guided by research questions. Whichever is appropriate should be described.

2.3 Recruitment

2.3.1 The description of the study population should include any and all characteristics or attributes of potential participants that are relevant to the research. Specific attention should be paid to those attributes that would suggest a level of vulnerability in the potential participants; e.g., literacy limitations, cognitive or physical impairment, extreme youth.

Justification should be provided for the sample size sought. For quantitative research this may mean power calculations, for qualitative work, a rationale for the estimated number of participants needed.

2.3.2 Researchers should describe how they, or others on their behalf (e.g., staff of a community service provider distributing recruitment brochures, IT managers circulating an email), will be using these recruitment methods. Researchers should be careful to address issues surrounding recruitment that might relate to the voluntariness of participation. For example, TAs wishing to involve students as participants in research must clearly demonstrate how they have mitigated any undue or coercive influences (see TCPS 3.1).

Recruitment instruments including such items as posters, media advertisements, brochures, email text or letters, etc., must be appended to the application. Where oral recruitment is proposed, scripts guiding this process should be presented. Whatever participants see or hear must be presented to the REB to review.
Specific inclusion and exclusion criteria (e.g., age, profession, medical condition) should be stated, and if results are intended to be generalizable broadly, exclusion of population groups should be justified.

Where screening methods are used to select participants, these should be described, along with how the data from these measures will be used, stored and destroyed.

2.3.3 If the permission or support of organizations is needed (e.g., Aboriginal Band Council, School Board, director of a long-term care facility) for the researcher to be able to conduct recruitment and research activities, these should be described and letters of permission included in an appendix to the submission. Organizational permission is not always appropriate, particularly for critical inquiry (see TCPS article 3.6).

2.4 Informed Consent Process

2.4.1 The conduct of research involving humans requires that people be provided with the opportunity to give informed consent prior to participation in research. The process of obtaining this consent can be carried out in a number of ways, and where warranted, should be revisited during the research (where the research takes place over a protracted period, or where information emerges during research that might influence a participant’s decision to remain in the study).

Informed consent is commonly documented using a written consent form that the researcher reviews with participants prior to the start of the research. This document must provide potential participants with sufficient information about the research to ensure that they understand the procedures, tasks or activities in which they may be involved, and the risks and potential benefits of the research. It must also inform them of their rights with respect to participation, i.e., that research participation is voluntary and that they have the right to withdraw. Researchers must provide the consent form to people in advance of whatever activity they may be involved in (i.e., focus group, testing) so that potential participants have a chance to consider risks and benefits prior to engaging in any research activity.

The researcher should describe the consent process that will be used, including who will engage in it, when it will be done (in relation to when the research will take place) and where it will be done.

Where different groups of participants will be involved in different aspects of the study, a consent form specific to each group’s participation should be developed, to avoid confusion or misinterpretation.

Written and signed consent forms are not always appropriate, or may constitute a risk to research participants. In these cases, non-written consent may be appropriate and the process to be used in obtaining it and documenting it should be described. The TCPS (article 3.12) requires researchers to document non-written consent in some manner (e.g., audio recording, field notes). It may also be appropriate to leave the participants with a statement of information about the project and contact information for the researcher and the Research Ethics office.

For written and online surveys/questionnaires, no signatures are necessary if the consent form appears as the first page of the survey. In these situations, the participant’s act of completing and submitting the survey/questionnaire can be used to indicate consent.
Where it is not clear that potential participants have the capacity to provide informed consent, or if the research population is recognized as lacking the capacity to provide informed consent (e.g., young children, persons with a significant cognitive impairment), informed consent must be obtained from an individual who is responsible for decisions concerning the well-being of the participant (e.g. parent, guardian, caregiver). Where this impairment is temporary, researchers should describe how consent will be obtained from the participant when they are deemed to have gained decisional capacity. Where a participant lacking decisional capacity is able to provide assent for the research (i.e., demonstrate their willingness to cooperate with the researcher and take part in the research), this should also be sought. Researchers should provide a description in the application of the criteria that they will use to judge assent or dissent of a participant. With children, there is no age of consent for research in Nova Scotia, thus capacity is assessed on a case-by-case basis. The more invasive the study, the more it may make sense to have parental consent and youth assent. With less invasive studies, it is often appropriate to have youth consent, simply informing parents.

The process of consent is not limited to the initial discussion and signing of the consent form. In studies conducted over time, reconfirming consent is appropriate. During the course of the research, new information about the study, or knowledge regarding the risks of study procedures may be learned that should be disclosed to participants. It is the responsibility of the researcher to ensure that this is done. This would be achieved through submitting an amendment to the Research Ethics Board describing the changes to the recruitment or consent process; informing and reconfirming consent of those currently involved in the study; and modifying the consent process and/or consent form for new participants.

In some circumstances (e.g., Aboriginal research) it may be important to seek consent from the community as a whole in addition to getting consent from individual participants. It is the responsibility of the researcher to determine whether or not this is needed, and if so, to describe how such consent will be sought.

2.4.2 Participants should be given ample opportunity to withdraw from a study with no negative consequence. The researcher should discuss how participants may withdraw, and at what point this may no longer be possible (e.g. after study results are analyzed). The limits on withdrawal should be made clear in the application and in the consent form, including what will happen with participant data should they withdraw part way through the study.

2.4.3 In accordance with the TCPS (article 3.7A), there are specific situations where the REB may consider an exception to the requirement to seek prior participant consent for minimal risk studies. The conditions described in the TCPS must be met (minimal risk, adverse effects unlikely, impracticable, defined nature and extent of exception, and plan for debriefing). If a researcher would like to seek an alteration/exception to obtaining informed consent, s/he must describe how the proposed research meets each of the conditions described in TCPS article 3.7A.

2.5 Methods and Analysis

2.5.1 Describe the research measures to be used; a brief description of how these will fulfill the study’s objectives (i.e., how they link to the research questions or hypotheses) should be provided. Similarly, the merits of a particular qualitative methodology, in the context of the study’s intent, should be provided. The physical location of the study (e.g., where testing will be conducted, or interviews held) must be described. It is important to provide sufficient detail so that any limitations to confidentiality, or any safety concerns, can be identified.
A description of the procedures, tasks or activities in which research participants will be asked to take part must be presented so that the Board can clearly understand what participants will experience. Where many procedures are planned, a stepwise flow-chart or table (indicating procedures and their duration) may be helpful. This is especially important where multiple interactions are planned with some or all of the participants.

The researcher should estimate the time that participants will be asked to commit to the study. This will include time to review the consent form, time to complete the study measures, and any post-data collection activities, such as member-checking or data verification. The researcher should provide a total time for participation as well as a time estimate for each task.

The researcher should describe what data will be collected and how they will be collected. All research instruments should be described and/or appended (e.g., questionnaires, focus group/interview guides, standardized measures) along with information on psychometrics or trustworthiness (where appropriate).

Ethical principles require that researchers only collect the data needed to address the research questions. Therefore, where a number of instruments or demographic questionnaires are to be used, each must be justified in relation to the objectives of the study. Where video recording or audio recording is planned, the researcher should describe why this is necessary and how it will be done. Any plans to re-contact participants need to be described, where applicable. Any safety measures should also be described.

2.5.2 A brief description of the plans for data analyses (including any software and statistical tests that will be used) should be described. Describe how the proposed data analyses address the study’s primary objectives or research questions.

2.5.3 It is not necessary to offer compensation, incentives or reimbursement to participants for their participation in research. However, when offered, compensation for research participation is generally considered to be an honorarium or gesture of appreciation for participant contribution and/or expertise. Participants may also be compensated for inconvenience experienced. It is not intended to represent a payment in the sense of employment or fee for service. Compensation or incentives must not represent an undue influence that would induce a participant to accept significant risks that they otherwise would not (see TCPS 3.1).

Researchers are asked to describe how compensation will be handled in situations where participants do not complete the study. The Tri-Council Policy Statement, article 3.1 regarding voluntary consent, reads "the participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawing be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount" (TCPS 3.1 – Application (b)). An incremental compensation plan can be appropriate and should be clearly explained to participants, usually through the consent form.

The researcher should consider whether or not the research participant may incur expenses as a direct result of their participation in the research (e.g., transportation or dependent care costs). Efforts should be made to reimburse participants for these costs. If this is not possible, participants should be informed that such reimbursement will not be possible so that they do not have expectations that cannot be met.
2.5.4 If misdirection or deception will be used in the study, this must be justified, indicating why it is essential in order to achieve the study objectives (see TCPS article 3.7). Similarly, if information will be withheld from participants (e.g., the full intent of the study), this must be discussed along with the rationale for doing so. Where deception/misdirection/non-disclosure is used, the researcher should normally debrief participants regarding the true circumstances following their research participation. This would include disclosing what the deception or misdirection consisted of along with explaining the reasons for it. Similarly, information that has been withheld should be disclosed. A short written communication can be used, however, participants should be given the opportunity to withdraw themselves and their data from the study. A debriefing form must be appended to the application.

2.5.5 Describe the roles of each member of the research team in relation to the research study. Members of the research team should have the appropriate qualifications to carry out their duties in the study and these should be described (e.g., professional experience, methods courses, fieldwork or other experience or training). Where the local Dalhousie lead researcher is a member of a team with the principal investigator(s) located elsewhere, please indicate the extent of local researcher involvement.

2.6 Privacy and Confidentiality

2.6.1 Researchers have a responsibility to ensure that all data received from research participants is maintained in a confidential manner. Where the data is of a personal or sensitive nature, the Board may require the researcher to demonstrate significant confidentiality safeguards, including at a minimum the use of password protection and encryption of electronically-stored data. The researcher should clearly describe the kinds of information that will be collected. This is equally important where secondary use of data collected previously is being conducted; for example, by accessing client files, or personal records. Present a complete plan for data security, retention, storage and destruction (as applicable) over the life of the project. It is often appropriate to describe electronic data security measures, including file encryption and/or password protection. Where (and in what format) the data will be stored should be described, along with who will have access to it. If there are codes to be used that link the data from various sessions or sources, or to information that could identify participants (names, addresses etc.), security of these codes should be described. If there is to be remote transmission (e.g., electronic) from one location to another, this should be described as well as any security that pertains to this transmission. If a transcriptionist or translator has access to the data, s/he should sign a simple confidentiality agreement, a copy of which should be appended to the ethics submission.

The researcher should state how long the data will be retained. If data will be retained indefinitely, this needs to be clear to participants, along with how it will be rendered anonymous or de-identified. However long data may be retained, privacy of participants must be safeguarded. If data will eventually be destroyed, this process must be described.

2.6.2 Researchers should describe how data will be reported (e.g., as aggregate statistics, personal narratives) and what the implications of this are with respect to participant identification and data confidentiality. If the researcher plans to use quotations from research participants in results or presentations of the data, this should be stated. How this will be done without disclosing the identities of participants (unless participants agree to attribution) should be described. If willingness to be quoted is a condition of participation, this should be made clear in the consent process.
If the researcher wishes to attribute quotes by name, a rationale for this should be provided.

2.6.3 Where there are limits to confidentiality due to legal obligations (i.e., duty to disclose suspected child abuse or neglect, or the abuse or neglect of an adult in need of protection) or professional codes of ethics, this must be stated (when applicable to the study). A simple description of what the researcher will do in such a situation should be provided. This is advisable for research that may, inadvertently, cause such disclosures to be made, and it is imperative for research that specifically deals with issues of sexual or child abuse, domestic violence, elder abuse or ethical conduct of professional responsibilities.

2.6.4 If you propose using a survey company or software to help you collect, manage, store, or analyze data that is personally identifiable and accessible from outside of Canada, you must describe that use here. It is recommended that researchers make use of the Opinio survey tool available through the University’s Information Technology Services department, which meets the Board’s expectations with respect to electronic security.

Researchers must comply with the University Policy for the Protection of Personal Information from Access Outside Canada that defines the responsibilities of all members of the University community with respect to handling of personal information. “Personal information” means recorded information about an identifiable individual, including, but not limited to:

- name, address, telephone, email (personal not business);
- race, ethnic origin or religious political beliefs or associations;
- age, sex, sexual orientation, marital status or family status;
- any identifying number or symbol (examples: Dalcard ID, SIN, credit card, health insurance, drivers’ license);
- fingerprints, blood type, or inheritable characteristics;
- medical or personal history;
- educational, employment, financial, or criminal history;
- personal views or opinions.

Researchers should consult the full University policy for assistance in determining which provisions of this policy might apply to their research and what actions (if any) they must take to satisfy them. These should be reported briefly in this section of the application.

2.7 Provision of Results to Participants

2.7.1 Participants are often given the opportunity to see the results of the study, once it has been completed. This may be done in a number of ways, e.g., by giving a group presentation, sending a simple written summary to participants, providing the results on-line, using a website.

Participants who undergo testing as part of their research participation may wish to see the results of their tests. This may or may not be feasible. For instance, when measures to preserve confidentiality require that identifying information is removed from individual results, rendering them de-identified, or when data aggregation takes place prior to analysis, it may not be feasible to provide individual results. Also, there may be concerns (depending upon the nature of the tests conducted) related to the potential for misinterpretation or misuse of individual results (e.g., where results require expert
interpretation, or tests are screening tools but not diagnostic). Where it is appropriate and possible to give participants individual results, this should be done in such a manner as to enable clear interpretation by the participant, either independently, or with assistance provided by the researcher.

2.7.2 When data collected from a research participant indicates that the participant might be at risk (e.g., is demonstrating distress, may have a previously unknown physiological condition) the researcher has an ethical obligation to inform the participant that appropriate follow-up is available and/or advisable, and to provide some information to assist in this.

2.8 Risk and Benefit Analysis

2.8.1 Conducting a risk assessment of the proposed research is a vital part of the ethics submission. Researchers should be thorough but realistic in describing and estimating risks that are posed to participants in the study. Risks may be minor or significant; however the researcher is responsible for mitigating any anticipated research-related risks to the best of his/her ability. In all cases, the researcher must disclose to participants whatever risk, discomfort, or inconveniences the research might pose, including all known adverse effects (including physical, emotional, psychological, social or economic) to the participant, and any anticipated or potential harms or stressors (physical, emotional, psychological, social or economic) to the participant.

It is useful if the researcher integrates the concept of ‘minimal risk’ into the description of risk. The definition of minimal risk used in the TCPS (Chapter 2-B)) is: “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”

Risk has two components: harm and the probability of that harm. In describing risks, the researcher should discuss both, such as “there is a high probability that participants will feel emotional distress...” or “there is one chance in 10,000 that participants could experience cardiac arrest ...” Where possible these should be substantiated by references to prior research or to the literature.

Researchers should describe what steps will be taken to mitigate the risks posed. These could include specific safety precautions, screening protocols, or ameliorating actions (e.g., contact information for support services).

External factors, such as the cultural or socio-political environment that could affect the potential participants, should be described. For example, where a study is investigating a source of community conflict, the nature of the conflict needs to be described so that ramifications of the study on the safety of participants can be assessed. Where the cultural context is relevant to the methodology or consent process, potential risks should be discussed.

Sometimes the research poses risks to third parties or at the level of communities. For example, there can be the risk of stigmatization linked to exploring negative characteristics. The researcher should seek to identify such risks when they exist, and to determine whether or not there are any mitigating actions that could be taken. This is not to suggest that critical research should not be undertaken, rather that the assessment of risk should consider communities, as well as individuals or organizations, and the researcher should address these either through mitigation (where possible) or disclosure to participants where it is not possible to mitigate these risks.
2.8.2 Direct benefits and indirect benefits should be described. Direct benefits are those benefits that participant receives as a direct result of his/her participation in the research. Only those benefits that can be assured should be described (often there are none). For example, a free fitness test might be a direct benefit if it is provided to all participants. Anticipating that participants might learn about research methods, or have a positive self-reflective experience is not something that can be guaranteed, nor is this obviously a benefit to them. Care should be taken not to overstate direct benefits.

The indirect benefits of the study arise from the new knowledge, information, or insights that result from the research. Because the REB assesses whether the risks to participants are justified by the benefits of the research, the Board must be convinced that the research will yield some benefits. Indirect benefits may be framed in terms of new knowledge that will be gained as well as any benefits that might accrue to study participants. Indirect benefits should focus on benefits beyond the researcher.

2.9 Conflict of Interest

Conflicts of interest may arise in the form of relationships between researchers and participants (see TCPS 7.4). For example, when a researcher who is also an instructor or TA wishes to recruit students from his/her own class into a research project, or a supervisor wishes to recruit employees under his or her supervision, researchers hold a dual role. The researcher should describe how conflicts that may arise from dual roles will be mitigated and/or managed.

The researcher must also disclose whether or not any member of the research team has a relationship with the sponsor of the study that would place them in a conflict of interest. One example of such a conflict would be a researcher’s having financial interest in a company sponsoring the research, or in the outcome of the research itself. The applicant should describe how any such conflicts will be managed. Researchers must ensure that they comply with Dalhousie’s Policy on Conflict of Interest.

Real or potential conflicts of interest, including dual roles, must also be described to research participants in the consent process, along with a description of how conflicts will be mitigated or managed.

2.10 Research with Aboriginal Peoples

In first considering whether section 2.10 needs to be completed, researchers need to decide whether their research involves First Nations, Inuit and Metis People of Canada. The involvement of Aboriginal people can vary greatly from study to study. It can vary from exclusively involving Aboriginal participants living on Aboriginal land to only incidentally involving a few people who happen to be of Aboriginal descent but who are not the focus of research, and data will not be analyzed using their heritage as a variable of interest. In determining whether this section needs to be completed, researchers should consult the TCPS for a list of examples of study populations that actively or only incidentally involve Aboriginal individuals. In the former case, section 2.10 needs to be completed, but not in the latter case.

Those who want to conduct research with Aboriginal individuals need to follow explicit research guidelines. Chapter 9 of the TCPS describes these guidelines. If researchers want to conduct research
with Aboriginal participants, it is imperative that they study TCPS Chapter 9 before submitting an application to the REB.

In particular, the TCPS requires (1) evidence of community engagement in the research and (2) that researchers return results back to the community. Community partnerships take time. The extent of the community’s engagement can be minimal and the results returned to the community/participants can be as little as a brief summary. Community engagement can also be done as a co-partnership with the community such that members of the community become part of the research team. Likewise, returning results to the community can go as far as community ownership of data. Whatever the level of engagement, it must be described.

2.10.1 If the research clearly involves First Nations, Inuit and Metis People of Canada, then securing some kind of community engagement is required, as per TCPS 9.1 and 9.10. The extent of the engagement can vary depending on the degree to which there is an identifiable community with recognized leadership and how much the community wishes to be involved in the project. For example, community engagement for participants living in an urban setting might mean recruiting through an Aboriginal community centre. However, research to be conducted on Aboriginal land may require the involvement of the formal leadership. Irrespective of the extent of the community engagement, the onus is on researchers to provide details of the process and outcome to the REB. Researchers should append any supporting letters or formal research agreements developed with the community in question.

The TCPS allows for exceptions to the requirement for community engagement. Researchers must explain why their research does not require it, referencing the appropriate section(s) in TCPS 9.2.

2.10.2 Research involving First Nations, Inuit and Metis People of Canada may fall under the purview of a local Aboriginal research ethics committee. For example, in Nova Scotia, Mi’kmaw Ethics Watch approval is required to conduct research with Mi’kmaw people. Researchers should determine and explain whether or not they need to obtain such approval.

2.10.3 Those conducting research with First Nations, Inuit and Metis People of Canada must return results to the community in agreed upon form. Again, the extent to which results will be shared with communities will vary from project to project.

Describe the plan for returning results to the community and any agreements negotiated with regards to data ownership. If there are specific risks to the community or to participants involved, ensure that these have been addressed in section 2.8.1. Also, if raw data are to be shared with the community, it is imperative that participants are made fully aware of the extent to which their data will be shared. They should be fully informed regarding who will have access to data, whether the data will be identifiable or not, where it will be kept and in what form, and any limits on confidentiality. Researchers and relevant community members should develop a plan from the outset regarding data custodianship, data security over the life of the data, and whether data will be shared before or only after they are de-identified or anonymized (although even if identifiers are stripped, data provided by participants may be sufficient to identify them given the small size of some communities). Full disclosure to participants is essential so they have accurate expectations regarding the security and privacy of their data.
Clinical Trials

2.11.1 Deciding whether or not a study is considered a clinical trial and therefore requires clinical trial registration is the responsibility of the researcher. Researchers conducting clinical trials that involve patients from Nova Scotia Health Authority, the IWK Health Centre or the Horizon Health Network are advised to seek review (and registration) through those institutions.

A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes (TCPS Chapter 11; World Health Organization). Interventions may include drugs, procedures, devices, natural health products, changes in process of care, preventative care, manual and psychological therapies, behavioural interventions, dietary interventions, biological materials, etc. Clinical trials most often pertain to biomedical research but may also include such fields as health promotion, counselling, and exercise studies. The researchers are usually (though not always) clinicians, health care providers. Many medical and health science journals require evidence of trial registry before considering publication.

The TCPS (article 11.3) states: “All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE).” It further notes that “Researchers shall provide the REB with the number assigned to the trial upon registration.”

Trial registration minimizes unnecessary burden on human participants and avoids non-reporting of negative results. Registration can usually be completed “pending” REB approval. The Board expects researchers to ensure their reporting requirements regarding trial registry are met.

For more information, see ClinicalTrials.gov (http://www.clinicaltrials.gov) or the WHO International Clinical Trials Portal (see http://www.who.int/topics/clinical_trials/en/). The Health Canada Clinical Trials Database (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php) only includes some forms of drug trials. CanadaTrials.com is another Canadian option for registry. Clinical Trials should be registered by the site of the lead investigator, normally through the institution that also provides REB oversight of the trial.

2.11.2 If a novel intervention or treatment is being examined, a situation of clinical equipoise is expected to exist, in which the relevant expert community is genuinely uncertain regarding best treatment or intervention. To establish this situation, researchers should describe standard treatment or intervention, to indicate the justification for examining a novel approach. If placebo is used for a control group, rather than standard treatment, this must be well justified, as withholding effective treatment or care is unethical. Use of placebo must be scientifically sound and must not compromise participant safety or care.

2.11.3 The safety and risks of any experimental product, device or intervention are key to the ethical conduct of a clinical trial. Any information available concerning approved uses, safety information and contraindications should be provided. Researchers must indicate how use of the product, device or intervention for the proposed research differs from the approved use.

2.11.4 The researcher should describe the way in which blinding and/or randomization will be used for intervention assignment, data collection and analysis (if applicable). It is important that participants know they may be assigned to the control arm of a study.
2.11.5 Researchers are responsible for monitoring and reporting participant safety. A plan for safety monitoring and timely reporting must be described. This may include the establishment of a data safety monitoring board. Removal of individual participants should be considered and interim analysis may be appropriate to enable study amendment, early unblinding or early study cessation.

Any information available concerning the conditions under which a study will be stopped early, or a participant may be removed before study completion, should be described here and in the consent documents.

The potential effects of early trial closure on participants should be mentioned, if relevant. It may also be appropriate to briefly mention any options for making available interventions that prove efficacious. If there are no such options, this should be made clear to potential participants in the consent documents (e.g., participants may find an intervention works for them, and they should know if there is no way to access that intervention post-study completion).

Provincial, national and international guidelines govern safety monitoring in clinical trials. It is the responsibility of researchers to be aware of any guidelines that apply to their research and apply them (see TCPS chapter 11).

2.12 Use of Personal Health Information

2.12.1 Personal health information includes any information collected for the purposes of providing healthcare services that is identifiable information about an individual’s health or that could reasonably lead to the identification of an individual. Use of this information is subject to the Nova Scotia Personal Health Information Act. It does not apply to statistical, aggregate or de-identified health information.

In this section, describe the personal health information required for this research and the sources of this information. Explain why the research cannot reasonably be accomplished without the use of this information. Describe how the personal health information will be used, and in the most de-identified form possible. Researchers must use the minimum amount of personal health information required to achieve the research goals.

2.12.2 Data linkage means the bringing together of two or more records of personal health information to form a composite record (e.g., health records and pharmaceutical dispensing records). Describe whether the personal health information will be linked; if so, describe the other information and how the linkage will be conducted.

Data matching means the creation of individual identifying health information by combining individual identifying or non-identifying health information or other information from two or more databases without the consent of the individuals who are the subjects of the information (e.g., patient records, employee records, and travel claims). Describe whether the research will include data matching; if so, explain why it is required.

2.12.3 Describe the reasonably foreseeable risks to privacy arising from the use of personal health information and how those risks will be mitigated.
SECTION 3. APPENDICES

3.1 Appendices Checklist

Append all relevant material to this application. This may include:

- Recruitment documents (posters, oral scripts, online postings, invitations to participate, etc.)
- Screening documents
- Consent /assent documents
- Research instruments (questionnaires, interview or focus group questions, etc.)
- Debriefing forms
- Letters of permission (Aboriginal Band Council, school board, director of a long-term care facility)
- Support letters
- Confidentiality agreements

3.2 Consent Form

Where it is clear that research participants have the capacity (i.e., decision making capability) to provide informed consent, the researcher must ensure that the information provided to research participants is presented in such a manner as to be easily and comprehensively understood. The language and terminology used in describing the research must clearly convey the objectives and methodology of the research project, and the risks and benefits to the research participant. It is normally recommended that consent forms be written for a Grade 8 level of reading comprehension.

Template consent forms are provided on the Research Ethics website to assist researchers in developing this important document. The template may be adapted as appropriate to the proposed research.