



Dalhousie Research Ethics Boards
Guidance for Submitting an Application for Research Ethics Review
For Prospective Research

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PROSPECTIVE vs SECONDARY USE FORMS

The prospective research application form should only be used if new data will be collected. For research involving *only* secondary use of existing information (such as health records, student records, survey data or biological materials), use the *REB Application Form – Secondary Use of Information for Research*.

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. 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 and research involving human biological materials.

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 Research team information

Lead researcher (at Dalhousie): 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 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 an official University email address (@dal.ca).

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, leave this blank.

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

1.2 Student submissions

Complete this section only if the lead researcher is a student, resident, or postdoctoral fellow. Identify your degree program (for example, BSc (Psychology), MD, MA (Health Promotion), PhD (Interdisciplinary)) and provide the name and contact information for the 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).

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 in section 1 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.

1.3 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'kmaq 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.

Scholarly/scientific peer review. If the project has been peer reviewed (such as during a funding competition), describe this review to the Board in this section.

Variation of previous Dal REB submission. If the current submission is a variation on, or extension of, a previously approved submission, please describe it here. Describe how this submission is the same as, and different from, a previously approved Dalhousie submission. Consider the research question, sample, recruitment procedures, consent process, methods, data retention, confidentiality etc. REB members may not recall, nor have access to, your prior submission; the summary here should be enough to assess whether new ethical issues need to be considered.

1.4 Funding

If the research project is funded, indicate the funding agency and award number. If it is not funded, check "Not Applicable".

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.

If you hold funding at Dalhousie University for which you were granted access to a portion of your funds in advance of REB approval through a release of funds agreement, please also indicate the date of this agreement in this section.

1.5 Attestations

Lead researcher: The lead researcher must indicate agreement with the attestation regarding the ethical conduct of the research. This section must be completed for all submissions.

Supervisor attestation: **Applicable only where the lead researcher is a student/resident/post-doctoral fellow.**

As part of the review process, the Board must ascertain whether there is scholarly merit, as research that will not yield trustworthy results is 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 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.

Please indicate if the lead researcher and/or student supervisor has completed the TCPS Course on Research Ethics (CORE) online tutorial. The online tutorial may be found through the Research Ethics homepage or at <http://tcps2core.ca/welcome>. 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 reference list should be appended to the application. 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.

For clinical trials, the proposed research should be presented in the context of a systematic review of the literature on the study topic.

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 are 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 are 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 **Phased review. A phased review requires the submission of separate ethics applications for different phases of a research study.**

Many study designs involve multiple steps. Often data are collected in earlier stages that informs the details of later stages. However, in most such cases **a phased review is not required.**

If the researcher is able to provide a plan for the entire project (including draft methods/instruments for later stages) a phased review is not required and **“not applicable”** should be selected. Ethics review for the entire project will be conducted and any subsequent changes or refinements to the methods/instruments will be reviewed as amendment requests.

However, if the researcher is unable to provide a plan for the entire project at the outset (including draft methods and instruments), a **“phased review”** should be requested. A phased review will only be considered when it is necessitated by the study design; piece-meal submission of a project that could be submitted as a whole, will not be considered.

Note that the REB must be able to review all aspects of a study in order to approve it. This includes study instruments. If draft instruments for later stages cannot be provided with the initial submission, a phased review will be necessary.

PHASED REVIEW PROCESS

PHASE 1:

- The researcher prepares a submission for Phase 1 of the study. The rationale and scholarly context for the entire study should be described in section 2.1.1, including an outline of the entire research plan in stages.
- In section 2.1.2 the researcher indicates which stage(s) is/are currently being submitted for review and approval in Phase 1. NOTE: The Board can only review and approve that portion of the study for which all necessary documentation is available.
- The remainder of the application should only describe the stage(s) under review in this Phase 1 submission. **Do not include details of subsequent phases as these will not be reviewed at this time.**

PHASE(S) 2+:

- At the completion of the research approved in Phase 1, and prior to advancing to the next phase, the researcher should submit the next phase of the study for review (as a new ethics submission).
- 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).

2.2 Research Question

Some studies are intended 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.

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.

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.

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, support, or cooperation of organizations, communities, or companies is needed (e.g., Indigenous 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 detailing their role in the research 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 (and according to the TCPS, Article 3.3), 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 researcher should consider whether the child/youth participant can appreciate the risks of participation and make an informed decision about participation.

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., Indigenous 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.

If there is a chance that the data may be used for other purposes in the future (e.g. used for additional research, or placed in a data repository), this information should be presented in the consent form.

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. It is helpful to indicate specific dates as cut-off points so participants can be clear about how long they have to withdraw their data if they so choose.

2.4.3 In accordance with the TCPS (article 3.7A), there are specific situations where the REB may consider an alteration 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 alteration, and plan for debriefing). If a researcher would like to seek an alteration/exception to obtaining informed consent, they must describe how the proposed research meets each of the conditions described in TCPS article 3.7A.

2.4.4 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 Methods and Analysis

2.5.1 Describe the study design and 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 participants.

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.

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.

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.

2.6 Privacy and Confidentiality

Researchers have a responsibility to respect participant privacy and ensure that all data received from research participants is maintained in a confidential manner. 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. Where the data are 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. See the [quick reference guide for storing personally identifiable research data](#). Completion of section 2.6 should provide a complete plan for data security, retention, storage and destruction (as applicable) over the life of the project.

2.6.1

- A) Describe who will have knowledge of participants' identities,
- B) Describe the level of identifiability of the study data (anonymous, anonymized, de-identified/coded, identifying) (see [TCPS Chapter 5A – types of information](#)) for each mode of data collection to be used.
- C) Describe who will have access to participants' data, and for what purpose. If a transcriptionist or translator has access to the data, they should sign a simple confidentiality agreement, a copy of which should be appended to the ethics submission.
- D) Describe how study documents and participant data (both hard copy and electronic) will be collected, handled, transported or transferred and stored during the data collection and analysis phase. 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. For electronic data, describe electronic data security measures, including file encryption and/or password protection. For hard copy documents, describe physical security measures.

2.6.2 Describe plans for long-term storage (how long data will be retained and where). However long data may be retained, privacy of participants must be safeguarded. If data will be retained indefinitely, this needs to be clear to participants, along with how the data will be rendered anonymous or de-identified. If data will eventually be destroyed, this process must be described.

If the data will be deposited in a data repository, complete section 2.13.

2.6.3 Researchers should indicate how quantitative and qualitative data will be reported and whether there are implications 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.

2.6.4 Where there are limits to confidentiality due to legal obligations (i.e., duty to report 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) ([TCPS 5.2](#)). 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. Note that in Nova Scotia the *legal* duty to report only applies to abuse or neglect (or suspicion of abuse or neglect) of a [child](#) or an [adult in need of protection](#). Other types of disclosure, such as those that may be required by a professional code of ethics, are not required by law and must be justified in the application and clearly explained in consent forms.

2.6.5 If you propose using a survey company or software to help you collect, manage, store, or analyze personally identifiable data, and use of the tool makes the data accessible from outside of Canada, you must describe that use here. It is recommended that researchers make use of the Opinio or RedCap survey tools available through the University's Information Technology Services department, which meet 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 Risk and Benefit Analysis

2.7.1 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 their 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.

2.7.2 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.

2.8 Provision of Results to Participants and Dissemination Plans

2.8.1 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 anonymized, 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.

2.8.2 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.

In research studies where material incidental findings (i.e. findings that have significant welfare implications for the participant) are likely, researchers must have a fully developed plan indicating how they will disclose these findings to the participant, or request an exemption to this obligation based on the impracticability or impossibility of such disclosure (TCPS Article 3.4).

2.8.3 TCPS Article 4.8 explains that “Researchers ...have an ethical responsibility to make reasonable efforts to publicly disseminate research findings in appropriate venues in a timely manner” (TCPS Article 4.8). Describe plans for dissemination.

NOTE: If the research involves an Indigenous community, dissemination plans must be negotiated with the community prior to beginning the research (TCPS Chapter 9) and documented in a research agreement.

2.9 Research Team

2.9.1 Describe the roles of each member of the research team in relation to the research study.

2.9.2 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).

2.10 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.

2.11 Research involving Indigenous Peoples

In first considering whether section 2.11 needs to be completed, researchers need to decide whether their research involves First Nations, Inuit and Metis People of Canada. The involvement of Indigenous people can vary greatly from study to study. It can vary from exclusively involving Indigenous participants living on Indigenous land, to only incidentally involving a few people who happen to be of Indigenous 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 ([*Article 9.2*](#)) for a list of examples of study populations that actively or only incidentally involve Indigenous individuals. In the former case, section 2.11 needs to be completed, but not in the latter case.

Those who want to conduct research with Indigenous individuals need to follow explicit research guidelines. Chapter 9 of the TCPS describes these guidelines. If researchers want to conduct research with Indigenous 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. **Communities can also lead projects.** Likewise, returning results to the community can go as far as community ownership of data. Whatever the level of engagement, it must be described.

2.11.1 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 Indigenous community centre. However, research to be conducted on Indigenous 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. Append any supporting letters from 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.

2.11.2 Research involving First Nations, Inuit and Metis People of Canada may fall under the purview of a local Indigenous research ethics committee. For example, in Nova Scotia, Mi'kmaq Ethics Watch approval is sometimes required to conduct research with Mi'kmaq people. Researchers should

determine and explain whether or not they need to obtain such approval. Information on the MEW review and approval process can be found here: <https://www.cbu.ca/indigenous-affairs/mikmaw-ethics-watch/>

2.11.3 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.

In advance of making a submission to the Dalhousie REB, researchers must develop research agreements with their partner communities and append the research agreements to the ethics submission. Research agreements must describe the plan for returning results to the community and any agreements negotiated with regards to data governance (see section 2.11.4). Participants must be made fully aware of the data management plan as articulated in the research agreement. They must be fully informed regarding who will have access to data, whether the data will be identifiable or not, where data will be kept and in what form, and any limits on confidentiality. Researchers and relevant community members must develop a plan from the outset regarding research dissemination, 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.

2.11.4 TCPS Article 9.8 discusses researchers' obligations to respect customs of individual communities, and this may mean that OCAP principles (ownership of, control of, access to, and possession) of research data and processes need to be negotiated with the communities. This section should explain if and how the researcher intends to incorporate these principles into the study design. Information on OCAP can be [found here](#).

2.12 Clinical Trials

2.12.1 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 Registry Platform (see http://www.who.int/topics/clinical_trials/en/).

Clinical trials should be registered by the site of the lead investigator, normally through the institution that also provides REB oversight of the trial.

Researchers are responsible for updating their trial registry in a timely manner.

2.12.2 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.

2.12.3 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.

2.12.4 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.

2.12.5 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).

2.13 Use of Personal Health Information

2.13.1 The NS [*Personal Health Information Act*](#) governs the use of personal health information. The Act does not apply to statistical, aggregate or anonymized health information. Personal health information is information collected in the course of receiving care from a health care professional. The Act defines personal health information as:

"personal health information" means identifying information about an individual, whether living or deceased, and in both recorded and unrecorded forms, if the information

- (i) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,*
- (ii) relates to the application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,*
- (iii) relates to payments or eligibility for health care in respect of the individual,*
- (iv) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,*
- (v) is the individual's registration information, including the individual's health-card number, or*
- (vi) identifies an individual's substitute decision-maker.*

In this section, describe the personal health information required for this research and the sources of this information. If the research involves personal health information subject to the Nova Scotia Personal Health Information Act, explain why the research cannot reasonably be accomplished without access to 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.

2.13.2 TCPS Article 5.7 discusses data linkage. Data linkage means the bringing together of two or more records of personal information to form a composite record. The identifiability of individuals *may* increase as a result of this process.

Indicate whether personal health information will be combined from multiple sources. If so, A) justify why it is required, B) describe how it will be done, and C) describe whether the linkage increases the identifiability of the individuals to whom the data pertains.

It is helpful to include an image or flowchart to illustrate the linkage process.

2.13.3 Describe reasonably foreseeable risks to privacy due to the use of personal health information and how these will be mitigated.

2.14 Data Repositories

2.14.1 If the researcher wishes to store data in a public data repository for use by the research community, then section 2.14 will need to be completed. If the specific repository is known (preferred),

it should be described including the types of data typically held there, and who has access (e.g. only researchers, only those with an account, the general public, etc.). Any relevant terms or conditions related to submitting data to the repository should be described, including the length of time the data will remain in the repository.

2.14.2 Provide details about the data set from the research that will be included in the repository, including whether the data are qualitative or quantitative data. Will the data be raw data or aggregate/summarized data? If raw data, will it be de-identified or anonymized? The process for de-identifying/anonymizing the data must be well-considered and explained to the REB. What security features does the repository use to protect personal and/or sensitive data from unauthorized access, where is the data stored when in the repository (e.g. where are the servers physically located), what back-ups are done on the data, are there other measures in place to mitigate any risks to participant privacy, etc.? Include all data fields that will be in the data set (as an appendix).

2.14.3 Some participants may wish to participate in research but not wish to have their data, particularly raw data, made available in a public repository. It is best practice to place minimal barriers to participation, such as a requirement to include data in a public repository. Therefore, the Board recommends not making inclusion of data in a repository a requirement of participation. If it is a requirement, the researcher should justify why that is the best course of action for the research. The researcher should describe the process for participants to opt-in or -out of having their data included in the repository.

SECTION 3. APPENDICES

Appendices Checklist

Append all relevant material to this application in the order they will be used. This may include:

- Reference list
- Permission or support/cooperation letters (e.g. Indigenous Band Council, School Board, Director of a long-term care facility, anyone whose permission you need to recruit participants or conduct research)
- Research agreements (required for research involving Indigenous communities)
- Recruitment documents (posters, oral scripts, online postings, invitations to participate, etc.)
- Screening documents
- Consent/assent documents or scripts
- Research instruments (questionnaires, interview or focus group questions, etc.)
- Debriefing and/or study results templates
- List of data fields included in data repository
- Confidentiality agreements

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.