



## **Dalhousie Research Ethics Boards**

### **Guidance for Submitting an Application for Research Ethics Review – Secondary Use of Information (and Biological Materials)**

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## PROSPECTIVE vs SECONDARY USE FORMS

The secondary use of information application form should only be used for studies involving data that already exist (or human biological materials already collected) and that were gathered for purposes other than the current research project. If the research also involves collection of new data, use the *REB Application Form - Prospective Research*.

Types of secondary-use research that require research ethics review include:

- Data sets compiled for other purposes (such as previous research, business, public administration, institutional record keeping, education or health care), which are not publicly available but can be obtained for research analyses.
- Individual records systematically maintained by an institution or governing body (such as patient records, student records, employee records, disability claims, sales data, billing records), which can be used for research purposes.
- Human biological materials collected for other purposes (such as previous research, educational purposes or materials surplus to a diagnostic exam or surgical procedure).

Secondary use of information **does not require ethics review** when the information is publicly available through a mechanism set out by legislation or regulation and that is protected by law (e.g., Statistics Canada files, the US National Health and Nutrition Examination Survey) or the information is in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy (TCPS [Article 2.2](#)). REB review is also not required for secondary use of anonymous information, or anonymous human biological materials (TCPS [Article 2.4](#)). Note that *anonymous* means the information **never had** identifiers associated with it; information that has been *anonymized* or *coded* may require REB review.

### 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 academic research projects. However, students should only be the named lead researcher on a research ethics application 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). In effect, 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 information or biological materials.

## 1.2 Student submissions

Complete this section only if the lead researcher is a student, resident, or postdoctoral fellow. Identify the 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 a University-level 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 (including human data and/or biological materials).

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, 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 may 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 they have 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, and the data/records/biological materials and methods to be used. This section is meant to orient Board members to the study and to explain the context for undertaking it. Include references to the literature to substantiate the researcher's description of why it is necessary to undertake this research; the reference list should be appended to the application. Emphasize what new knowledge is anticipated from this secondary analysis.

Indicate 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 data/materials 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.

### **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 is 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. These must be included in the submission.
- 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 Information Source / Identification**

**2.3.1** Describe the population included in the original source data (or biological material) collection, including relevant demographics. Who was included in the initial data collection? How many people did it include, and what is known about who those people were? Is the dataset time-limited (e.g., records were kept for specific years)?

Describe how the information was initially gathered, when, and by whom and for what purpose. If information was collected for research, it is relevant to indicate how participants were originally recruited, as it may affect the validity of the information to address current study goals (e.g., who was originally included and excluded in the data, or biological materials, collected?).

**2.3.2** By definition, secondary analysis relies on information (including human biological materials) that was gathered for another purpose. Explain how the purpose of the current research builds on and/or differs from the purpose for which the information (or biological sample) was originally gathered.

This may mean asking novel questions of information originally collected to address different questions, conducting analyses in innovative ways, combining data in new ways, examining some subsample of the data in greater depth, or drawing on data collected for administrative or institutional purposes in order to address research questions or hypotheses. The distinction must be made clear between the purpose for original collection and the use to be made of those data (or biological materials) in the proposed study.

**2.3.3** Explain why the data in this dataset, these records or these human biological materials, is suited to addressing the research questions or objectives. If a sub-sample will be drawn from existing dataset or existing records or existing biological materials to address the research goals, explain how the sub-sample will meet the study goals (e.g., only data from one year before and one year after a curriculum change, only data from the latest wave of a survey, only biological materials for a certain medical condition).

Explain and justify any inclusion/exclusion criteria in relation to the study objectives (e.g., student debt loads on a self-report survey, but only full-time students will be included because they best address the research questions). Mention how it will be possible to identify and select the data for the subsample; this is most significant for research involving individual records, rather than existing datasets.

**2.3.4** Describe the steward/custodian(s) of any records, databases or biological materials to be accessed. The data steward is the body or institution that has responsibility for authorizing access and

disclosure of data to third parties; the data custodian is the body or institution who has responsibility for data storage and integrity. Both roles may be played by the same body/institution. Some examples might be: an institution that holds individual records or materials; researchers who conducted an original survey, or collected biological materials; an administrative body that regulates access to publicly accessible data.

2.3.5 Permission may be needed from the steward/custodian of the data or biological materials, Evidence of agreement from the institution or organization signals a respectful relationship and study feasibility. It is expected that such approvals are secured *prior* to the submission of the research ethics package to the REB. If prior approval is not possible, please explain why.

2.3.6 TCPS Chapter 9 must be followed if the secondary analyses concern Indigenous people in significant ways (e.g., drawing a subsample of Indigenous cases from a larger dataset, or using all individual records available but analyzing differences between Indigenous and non-Indigenous cases on scores or outcomes).

In such instances, researchers are required to engage with relevant Indigenous communities. The TCPS stipulates that the degree of collaboration required between researchers and Indigenous communities varies depending on context and the nature of the research, but it is the researcher's responsibility to describe appropriate community engagement. Where applicable, research agreements concerning information access, use and/or ownership (either as part of the original data or biological materials collection, or as part of the proposed secondary analysis) those must be appended at the time of initial REB submission.

Depending on the extent of involvement of Indigenous data or biological materials, ethical approval from any Indigenous ethics review group may be required. It is the researcher's responsibility to investigate whether this would be required and the Board should be informed about this.

2.3.7 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 should be negotiated with the communities. This section should explain if and how the researcher intends to incorporate these principles into the study design.

## **2.4 Informed Consent**

2.4.1 If data or biological materials were originally collected for research purposes, it is important to describe how informed consent was handled in the original research. It is key for the Board to understand what original research participants consented to, and whether their original consent can be considered to cover the secondary analyses proposed. If the original consent form is available, it should be appended.

Generally secondary analysis concerns research questions or analyses that were not part of the original research, yet ethically, it is important to ensure people's data and/or biological material is not being used for purposes they might never have imagined and to which they might not have consented.

2.4.2 When individual records (e.g., health records, educational records) are the data source for analysis, it may be possible to obtain consent from the individuals affected before using their identifiable information that was collected for other purposes. The TCPS (Chapters 5 and 12) describes

conditions under which an exception to the requirement for obtaining consent may be approved. If individual records or materials will be used, and individual consent will not be sought, researchers must explain how they meet each of these criteria.

## **2.5 Collection and Analysis**

2.5.1 Briefly discuss the information to be captured from the original dataset or collection of biological samples, including the data fields to be used. If an existing (administrative or research) dataset will be employed, indicate the variables to be used for the proposed analyses. Justify the use of these data in relation to the study purposes.

If biological samples will be processed or analyzed, describe the methodologies and what data will be captured.

If a data capture sheet will be used for systematic review of individual records or biological materials, it should be appended. If a dataset is being used, append a list of variables that will be used.

2.5.2 Briefly describe how the secondary analysis will be conducted. Indicate how the proposed data analyses address the study's primary objectives or research questions.

## **2.6 Privacy and Confidentiality**

### 2.6.1

A) The level of identifiability of data or biological materials held in the original dataset should be indicated. The levels are:

- Anonymized - all identifiers have been removed and there is no key-code linking data/materials with individuals
- De-identified - a key-code linking data/materials with individuals exists but is not available to the person accessing the data
- Identifying – information in the dataset directly or indirectly identifies individuals

B) Describe who will access the original dataset/ biological material collection to extract the data or samples needed for the research. What is their role or qualifications? For example, if patient records are being drawn from a health care clinic, and only those with a specific diagnosis are needed for the proposed analyses, who will sort through all patient records to extract only those eligible, and how will this be done in ways that protect the privacy of all patients?

### 2.6.2

A) Similarly, the level of identifiability of the data or biological samples that will be extracted for the research should be described. It is best practice to collect information at the lowest level of identifiability possible to meet study objectives. Data may be identifiable to the steward/custodian of the data, but the researcher might only be given access to anonymized or de-identified/coded data or biological materials (e.g., provincial medical records identified by health card number, but health card numbers will be replaced with study ID numbers prior to giving data to the researcher; or a school staff member could black out all identifiers on hard copies of student records before copying them for the researcher's use).

Identifying information contains direct or indirect identifiers. Direct identifiers would tell any reader who the record pertains to (e.g., name, contact information, student number, SIN, health number). Indirect identifiers could be combined to discern who a record belongs to (e.g., date of birth, sex, postal code, ethnicity). If identifying information is being collected, justify why each item is needed to conduct the research.

B) Different research team members may have access to data at different levels of identifiability. This should be briefly discussed. Only those who need access to data for analyses should have access (e.g., one team member could enter all data from individual records into a spread sheet, and the rest of the team only accesses the de-identified spread sheet).

2.6.3 The NS [\*Personal Health Information Act\*](#) governs the use of personal 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:

*...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.*

The Act does not apply to statistical, aggregate or anonymized health 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.

2.6.4 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.

Describe whether information will be combined from multiple sources. If so, justify why it is required, how it will be done, and describe the risks to identifiability/privacy of the individuals to whom the data pertains.

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

2.6.5 If data will be collected or sent outside Canada, or software will be used with data that is personally identifiable and that software is accessible from outside of Canada, describe that here.

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: Dalcad 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.

These responsibilities relate to the collection, storage, analysis and management of personal information about identifiable individuals, and apply when transporting or transferring information, or when using non-Canadian software (e.g., where the company could access confidential data during remote trouble-shooting of software problems).

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.

2.6.6 Describe the steps by which the privacy and confidentiality of the information will be maintained during the study. 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.

Describe how and where study documents and data (both hard copy and electronic) and materials will be collected, handled, transported or transferred and stored during the data collection and analysis phase. [Plans for long-term storage after data analysis should be described in section 2.6.7.]

For electronic data, describe electronic data security measures, including file encryption and/or password protection. See the [quick reference guide for storing personally identifiable research data](#). For hard copy documents or biological samples, describe physical security measures.

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 biological samples will be transferred between sites, explain why and how this will be done securely.

If there are codes to be used that link the data to information that could identify participants (names, addresses etc.), security of these codes should be described.

2.6.7 Describe plans for long-term storage (how long data or samples will be retained and where). However long data may be retained, privacy of participants must be safeguarded. If data will be retained indefinitely, explain this along with how the data will be rendered anonymous or de-identified. Researchers should discuss plans for use of stored data or samples beyond the current study. If data will

eventually be destroyed, this process must be described. If the data will be deposited in a data repository, complete section 2.10.

## **2.7 Provision of Results to Participants and Dissemination Plans**

2.7.1 If applicable, participants who have contributed their data or samples to the research may be 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. Describe if/how you will share the study results.

2.7.2 If applicable, if data indicates that the participant might be at risk (e.g. 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).

### **2.7.3**

A) 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.

B) Indicate how the data will be presented during dissemination in terms of level of identifiability (e.g. aggregate/summary data vs. individual data).

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 the research agreement, which must be appended to the initial REB submission.

2.7.4 Discuss any potential risks to individuals arising from dissemination. Sometimes the research poses risks at the level of communities or collectives (e.g. geographic communities, schools, professions, ethnic groups, medical conditions, etc.). For example, there can be the risk of stigmatization linked to the exploration of negative characteristics (e.g., people in a geographic area are prone to particular health conditions, which affect insurability). 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 (e.g., masking communities’ identities, in some cases). 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, and the researcher should discuss the extent to which mitigation is possible.

## **2.8 Research Team**

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

2.8.2 Members of the research team should have the appropriate qualifications to carry out their duties in the study and these should be briefly described (e.g., statistics training, methods courses, clinical or educational or other experience).

## 2.9 Conflict of Interest

Conflicts of interest may arise when researchers are seeking consent for use of individual records, and they have ongoing relationships with the individual affected (e.g., healthcare providers who seek consent for use of records from their own patients, instructors who seeks consent for use of student records from their students). The researcher should describe how these conflicts will be mitigated and/or managed.

The researcher must 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, along with a description of how they will be mitigated or managed.

## 2.10 Data Repositories

2.10.1 If the researcher wishes to store data in a public data repository for use by the research community, then section 2.10 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.

2.10.2 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/summary 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).

2.10.3 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, therefore, the Board recommends not making inclusion of data in a repository a requirement of participation. If it is a requirement, the researcher should provide a justification as to 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. This may include:

- Reference list
- Steward/Custodian permission letters, support/cooperation correspondence
- Research agreements (required for research involving Indigenous communities)
- Original and/or new consent documents
- Data capture sheet/list of data fields, variables, survey items
- Flow diagram outlining data collection and linkages
- List of data fields included in data repository

### Consent Form Templates

Where researchers will obtain informed consent from individuals for use of personal records or biological materials, 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 included on the Research Ethics [website](#) to assist researchers in developing this important document. The template may be adapted as appropriate to the proposed research.

If consent was obtained for the original collection of the data, append the original consent documents.