Dalhousie Research Ethics Boards

Guidance for Submitting an Application for Research Ethics Review – Secondary Use of Information (and Biological Materials)
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Section 1. ADMINISTRATIVE INFORMATION

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

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

Health Sciences REB – reviews research dealing with medical, dental or health and mental health related topics 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.

The application form for review of Secondary Use of Information 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 current research project. No additional humans will participate in the study. 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 publically 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 that is publicly available does not require ethics review when the information is legally accessible to the public and appropriately protected by law (e.g., the US National Health and Nutrition Examination Survey, Statistics Canada public use files) or the information is legally accessible and there is no expectation of privacy (TCPS 2.2).

1.1 Dalhousie researcher

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

Students may be considered to be the lead researcher for their 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 the official University email address.

The study start and end dates should indicate when you plan to begin and end the parts of your research that involves human information or biological materials.

1.2 Student submissions

Complete this section if the lead researcher is a student. Identify your degree program (for example, BSc (Psychology), MD, MA (Health Promotion), PhD (Interdisciplinary)) and provide the name and contact information for the 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 (minimal risk) thesis research

Undergraduate students conducting minimal risk thesis research should initially submit their application for unit-level review (to obtain department, school or faculty research ethics approval) prior to submission to the university’s Research Ethics Board. Submissions that have received unit-level approval (indicated on the front page of the application form) are eligible for a streamlined review by the Research Ethics Board. The exceptions are research that is more than minimal risk, or where unit-level review is not available, in which case the research ethics application may be submitted directly to 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
Describe the custodian(s) of any records, databases or biological materials to be accessed and the status of approval for use of this information. It is recommended that such approvals are secured prior to the submission of the research ethics package to the REB.

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.

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

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

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

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

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

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

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

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

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

Section 2. PROJECT DESCRIPTION

2.1 Lay Summary

2.1.1 In lay language (plain language suitable for educated non-experts in the field), briefly describe the rationale, purpose, and study objectives, hypotheses or questions. 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.

2.1.2 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.

2.2 Information Source / Identification

2.2.1 Describe the population from the original 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, or a survey was conducted over a particular timeframe)?

Describe how the information was initially gathered, when, and by whom. 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?).
2.2.2 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. (e.g., if patient records are being drawn from a number of health care clinics, 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? If only portions of the patient record are needed, how will those be extracted while restricting unnecessary access to the remainder?).

2.2.3 Permission may be needed from the custodian of the data or biological materials, such as an institution that holds individual records or materials, the researchers who conducted an original survey, collected the biological materials, or an administrative body that regulates access to publically accessible data. Evidence of agreement from the institution or organization signals a respectful relationship and study feasibility.

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

In such instances, researchers are required to engage with relevant Aboriginal communities. The TCPS stipulates that the degree of collaboration required between researchers and Aboriginal communities varies depending on context and the nature of the research, but it is the researcher’s responsibility to describe appropriate community engagement or plans for engagement. If there are 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 should be appended.

Depending on the extent of involvement of Aboriginal data or biological materials, ethical approval from any Aboriginal ethics review group may be required. The Board should be informed about this.

2.3 Collection and Analysis

2.3.1 Briefly discuss the information to be captured from individual records or 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 a data capture sheet will be used for systematic review of individual records or biological materials, it should be appended. If a dataset if being used, appending a list of variables that will be used is helpful.
2.3.2 Detail how the secondary analysis will actually be conducted.

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

2.4 Informed Consent

2.4.1 If data or biological materials were originally collected for research purposes, when possible 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, sales records, educational records) are the data source for analysis, it may be possible to obtain consent from the individuals affected before using their private information that was collected for other purposes. The TCPS (Chapters 3, 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.

2.4.3 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 personal health information.

2.5 Privacy and Confidentiality

2.5.1 The level of identifiability of data or biological materials should be described. It is ethical to collect information at the lowest level of identifiability possible to meet study objectives. At one extreme, data was only ever anonymous, no one ever knew who respondents or participants were. Data may once have been identifiable, but has since been anonymized (there is no way to link it back to any individual identities). Data may be identifiable to the custodian of the data, but the researcher will only be given access to de-identified data or biological materials (e.g., provincial medical records identified by health card number, but those numbers will be replaced with study ID numbers prior to giving data to the researcher).

Identifiable 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). Justify why each item is essential to conduct the research. The risk attached to indirect identifiers varies with context; gathering age and gender and postal code may not pose a risk for a national study of 30,000 voters, but it may in a study of Canadians with an unusual genetic condition.

2.5.2 Describe whether information will be combined from multiple sources. If so, justify why it is required and how it will be done.

**Data linkage** means the bringing together of two or more records of personal information to form a composite record. Describe whether personal information will be linked between data sets; if so, describe the other information and how the linkage will be conducted.

**Data matching** means the creation of individual identifying information by combining information or from two or more databases *without the consent* of the individuals who are the subjects of the information. Describe whether the research will include data matching; if so, explain why it is required.

Both of these processes increase risks to privacy by compounding the amount of information compiled about any individual. Describe these risks and how they will be mitigated.

2.5.3 Describe the steps by which the privacy and confidentiality of the information will be maintained throughout the research process. It may be helpful to include an image or flowchart to illustrate this process.

In keeping with the identifiability of the information being used – or the identifiability of the information constructed through linkages or matching – indicate how individual privacy will be maintained. (e.g., postal codes will be replaced with province of residence; a school staff member will black out all names on hard copies of student records before copying them for the researcher’s use).

Indicate the steps that will be taken to protect the security of directly or indirectly identifiable information, including access to data, physical security, and technical (electronic) security. 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 spreadsheet, and the rest of the team only accesses the de-identified spreadsheet). Discuss what will be done with hard copies of data after entry into electronic form. Discuss what will be done with biological materials after analysis. Discuss protection of electronic data through encryption, or password protection. Loss or theft of USB keys and laptops is a risk.

When data is exchanged electronically, within a research team or between teams, risk of breach of confidentiality can increase significantly. If data will be transmitted between sites, explain why and how this will be done securely. If biological samples will be transferred between sites, explain why and how this will be done securely.

2.5.4 If data will be 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: 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.

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.

2.5.5 Different research team members may have access to data at different levels of identifiability. This should be briefly discussed.

2.5.6 When individual records or samples will be used for analysis, and data will be extracted from those records or samples, specify how they will be stored securely, respecting confidentiality, how long data or sample will be retained, and in what formats or conditions. If there are plans to retain data or materials for an extended time, or indefinitely, it should be retained in as de-identified a form as possible. If it will be destroyed eventually, this should be done in a way that protects confidentiality. These plans must be described.

When using existing datasets or samples, researchers should make clear whether they are accessing the data or samples at another location, and simply storing the analysed results themselves, or if they are obtaining a copy of the raw data or obtaining biological samples in whatever format to store at their own research site. If the latter, data/sample security must be addressed. The degree of de-identification or anonymization must be described, as well as procedures for this. If data or samples will be destroyed after study completion, discuss how. If data or samples will be retained, researchers should discuss plans for retention and use of stored data or samples beyond the current study.

2.6 Dissemination of Results / Individual or Collective Risk

2.6.1 Even when data or biological materials are identifiable during data collection and analysis, in the process of dissemination results are often (further) de-identified or aggregated to further mask identities. Discuss the extent to which results will be identifiable.

2.6.2 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.

2.7 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 form 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.

Section 3. APPENDICES

Appendices Checklist

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

- Original and/or new consent documents
- Permission letters, support letters
- Research agreements
- Data capture sheet/list of data fields, variables, survey items

Consent Form

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.