Research Ethics
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linked here

The prospective research application form should only be used if new data will be collected. For research involving secondary use of existing information (such as health records, student records, survey data or biological materials), use the

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

: Dalhousie University has two Research Ethics Boards. The assignment of the Board that will review a particular project is done according to the subject

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, and provide contact information. If there is not a contact person, leave this section blank.

The study start and end

participants in those aspects of their everyday life that relate t2 ůKŜ ǋŜăŜl·ǋŎKΦέ όTCPS2 Chapter 2-B). When in doubt about whether or not research may be considered minimal risk, please consult with Research Ethics.

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 review (such as a ꜩƪꝉΥ l·lj 9ůKics Watch) in addition to Dalhousie University. Complete this section to describe to the REB any other ethics review required for the project and

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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.

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 [redacted]dology for the next phase(s), any instruments or consent forms to be [redacted](s).

S[redacted]e studies [redacted]ntended to address specific research objectives, while others are more exploratory or in[redacted]ctive, guid[redacted]y research questions. Whichever is appropriate should be described.

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 sugg[redacted] level of vulnerability in the potential participants; e.g., literacy [redacted]ve or p[redacted]l impairment, extreme youth.

Specific inclusion and exclusion criteria (e.g., age, profession, medical condition) should be stated, and if results are inte[redacted]d to be generalizable broadly, exclusion of population groups should be justified.

[redacted]d be provided for the sample size sought. For quantitative research this may [redacted]lations, for qualitative work, a rationale for the estimated number of participants needed. Include the minimum number of participants needed to yield valid research results, and also a maximum number; it is best ethical practice to avoid collecting data from individuals if their data are not needed to complete the research objectives (i.e. do not over-sample). [redacted]

2.4.1 If the permission, support, or cooperation of organizations, communities, or companies is needed (e.g., course instruct

as an appendix. 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.

2.4.3 State clearly who will be responsible for conducting recruitment. Describe how this/these person(s) will be using the recruitment methods/tools identified in section 2.4.2 (e.g., staff of a community service provider distributing recruitment brochures, IT managers circulating an email, lead research putting up posters around campus, etc.). Researchers should be careful to address issues surrounding recruitment that might r

B) 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 ensur

identifiability, and privacy of participants, and the security of their personally identifiable information.

Different recording software will have different security features and safeguards, so the specific recording tool or software must be identified.

If recording participants is the preferred way to record data but someone could participate without being recorded, explain if adjustments to the data collection process will be undertaken. For example, if it is preferred to audio-record an interview but the participant preferred not to be recorded, perhaps hand-written notes would suffice.

2.6.3 Transcribing focus groups, interviews, or other recorded sessions is common practice. Researchers may opt to transcribe by hand or hire someone to transcribe by hand. Increasingly transcription software is used to accomplish this task. Whatever method is used should be described and the person doing it (if applicable) should be identified. If someone outside the research team will conduct transcription a transcriptionist agreement should be used (templates available on the research ethics website). Any software that is used should be specifically named. The use of transcription software can have implications for participant privacy, particularly if the recordings and/or completed transcripts are accessible from outside Canada.

2.6.4 A 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 adŘŴŠăă úKŜ ăűdzŘèůă LJrimary objectives or research questions. Explain how all data collected from participants will be used to address the research questions/objectives.

2.6.5 It is not necessary to offer incentives or reimbursement to participants for their participation in research. However, when offered, incentives 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. Incentives must not represent an undue influence that would induce a participant to accept significant risks that they otherwise would not (see TCPS2 3.1).

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kinds of information that will be collected. Where the data are of an identifiable, personal or sensitive nature, the Board may require the researcher to demonstrate significant confidentiality safeguards, including at a minimum the use of encryption of electronically-stored data. See the quick reference guide for storing personally identifiable research data. Completion of section 2.7 should provide a complete plan for data management, security, retention, storage and destruction (as applicable) over the life of the project and for the full life-cycle of the data.

2.7.1

A) Describe who will have knowledge of participants identities at any point in the research process. Identify anyone (including researchers, other participants, other people not involved in the research, etc.) who will see a participant participate, who will know a participant's name or have access to other identifiable information about the participant, or who will interact with a participant face-to-face.

B) Describe the level of identifiability of any study data or documentation (anonymous, anonymized, de-identified/coded, identifying) (see TCPS2 Chapter 5A – types of information) for each mode of data collection to be used and at all stages of the research.

Often there is a point where the data will be de-identified (before analysis, for example), so while the data may have originally been identifiable, it becomes de-identified at some point in the process.

C) Describe who will have [illegible], 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. It is common for supervisors to have access to their student researcher's data to assist with analysis.

management.

published] etc.)

B) Identify t

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. Ordinarily, obtaining informed consent from participants

gain access to the data?

2.8.6 Provide details about the data set from the research that will be included in the repository. For instance, are the data 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. Describe these conditions here and append an outline of the fields that will be included in the final data set.

2.9.1 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 integrateă ůKŜ ŎƵŶŎĞƉƚ ŽĨ ΨŵŝŶŝŵĂů ƌŝƐŬΖ ŝŶƚŽ ƚŚe description of risk. The definition of minimal risk used in the TCPS2 (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 discuăă ďŽƚŚ ăƐƉĞĐƚƐ ;Ğ͘Ő͕͘ ͞ƚŚĞƌĞ ŝƐ Ă ŚŝŐŚ ƉƌŽbability that participants will feel emotional distrĞƐƐ͘͟ Žƌ ͞ƚŚĞƌĞ ŝs one chance in 10,000 that participants could experience cardiac arrest͘͟ ² ǁŚĞƌĞ possible these should be substantiated by references to prior research or to 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

2.9.2 The following excerpt from the TCPS2 (Chapter 2) describes community risk and the type of information that should be provided in the REB application:

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 reăŜI·ŉŴǑKŜŉŒă 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 wiűK 5I·fK2ɗžλŜŒă _____.

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.

In first considering whether section 2.13 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 TCPS2 (Article 9.2) for a list of examples of study populations that actively or only incidentally involve Indigenous individuals. In the former case, section 2.13 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 TCPS2 describes these guidelines. If researchers want to conduct research with Indigenous participants, it is imperative that they study TCPS2 Chapter 9 before submitting an application to the REB.

In particular, the TCPS2 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 thŜ Ŏ2ŸŸɗzyλúèŒă ŜyƎagement 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.

2.13.1 If the research clearly involves First Nations, Inuit and Metis People of Canada, then securing some kind of community engagement is required, as per TCPS2 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.

Additionally, append any supporting letters from the community in question.

The TCPS2 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 TCPS2 9.2.

2.13.2 Research involving First Nations, Inuit and Metis People of Canada may fall under the purview of a local Indigenous research ethics committee

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be appropriate to briefly menti efficacious.
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documents (e.g., participants m w if there is
no way to access that intervent

Provincial, national and interna t is the
responsibility of researchers to apply them
(see TCPS2 chapter 11).

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identifiability of the individuals to whom the data pertains.