VERSION: July 2024

STFX Research Ethics Board (REB)
Secondary Use of Data Application Template

Do NOT submit this form, you must submit using the ROMEO portal.

This document is provided so that you may **review** all questions / information requested, before beginning your online submission. You may also wish to use this template, first, to develop the content of your submission, and then, when satisfied, cut and paste the information in each of your answer boxes into the appropriate answer boxes in the online form. **NOTE**: Character count limits apply in all cases – the character limits (including spaces) are provided for each relevant answer box, below.

Secondary Use of Data
According the TCPS 2(2022; p. 19), "secondary use of data refers to the use in research of information or human biological materials originally collected for a purpose other than the current research purpose." This could include data sets that have been collected for other purposes (e.g., previous research, institutional record keeping, health care) that are not publicly accessible but can be obtained for research purposes.

Note: REB approval is not necessary if data or documents intended for use are publicly available (e.g., Stats Can data sets). See Article 2.2 of TCPS 2 (2022).

Instructions
St. Francis Xavier University academic staff (i.e., faculty, lab instructors, nurse educators, Coady Program Staff, Librarians, adjuncts, etc.), Honours, Master's, and PhD students who intend to engage in secondary use of data must provide the University's Research Ethics Board (REB) with this completed application before conducting secondary analysis.

Please consult the TCPS 2 (2022) Chapter 5 (Privacy and Confidentiality), Section C (Consent and Secondary Use of Information for Research Purposes) before beginning any secondary research.

All StFX affiliated applicants who are principal investigators and co-investigators must complete the Tri-Council Course on Research Ethics (2022) (CORE 2022) and must provide the certificate obtained upon successful completion with each application submitted. Other StFX affiliated team members including research assistants, collaborators, etc. are strongly encouraged to complete CORE 2022.

Please note the following:
1. Please ensure all attachments to your application are included in **a single PDF document** and all pages **numbered consecutively.**
2. Incomplete applications will be returned and may not be considered if submitted after the deadline.
3. The REB endeavors to review applications in a timely fashion; however, researchers realistically should allow **4-6 weeks** for the review process to be completed (in most instances, this includes time for revisions).
4. Applications will normally be reviewed at the first scheduled meeting of the REB following the receipt of the application, as long as it is received by the submission deadline as posted on the REB website. **Please note:** The REB does not meet in July or August.
5. The REB operates within the **Tri-Council Policy Statement Guidelines**. Please consult these for detailed discussion on the various ethical issues raised.
6. Suggestions about the preparation of Invitations to Participate and of Consent/Assent Forms are provided in a separate document titled **Guidelines and Examples for Invitation to Participate and Consent Forms**.
7. Ethics approval is required for all undergraduate research with human participants:

a. **Honours Students**: in accordance with Tri-Council policy, the University Research Ethics Board must approve all Honours students' research with human participants. Honours students complete and submit their application, **using the form found here**, to their departmental or program Research Ethics Committee (REC) first. Upon completion of its review, the chair of the departmental or program REC signs the application and sends it to the student. The student then uploads the file and related information through the **ROMEO system** for final deliberation and approval by the REB. Students list their **Supervisors** as "co-investigators" in the **Project Team** tab when submitting to the full REB.

b. This two-part process is intended to recognize departmental expertise in subject areas and to meet Tri-Council guidelines. The StFX REB does not wish to delay Honours students' research, so every effort is made to review these projects in an efficient manner. However, special attention will be paid to research projects involving high risk and/or particularly vulnerable groups of participants.

c. **Other Undergraduate Research**: Ethics approval for other undergraduate research and for course-based research is reviewed at the departmental level only by departmental Research Ethics Committees.

It is important to ensure that your submission is **free of spelling, grammatical and typographical errors**. Applications found to contain multiple errors may be returned to the researcher for revisions prior to being reviewed by the board.

1. Instructions

Question	Answer
Is this an application for either a Masters' or PhD student project?	
If yes, it is expected that supervisors review both the application and supporting documents. Has the Supervisor and/or Supervisory Committee approved the project?	
If yes, provide the date of approval from the Supervisory Committee.	
Is this an application for an undergraduate Honours thesis project?	
If yes, has the Department/Program Research Ethics Committee approved the project?	
If yes, provide the date of approval from the Department/Program Research Ethics Committee.	

2. Other REB Approvals

#	Question	Answer
2.1	Will application for ethical approval of this research be required from other Research Ethics Boards, in addition to StFX REB?	
2.2	If Yes, to which REBs do you plan on submitting and in what time frame? (1,000)	
2.3	Have you already submitted an application to another REB for this project?	
2.4	If Yes, have you received approval for this project?	
2.5	If the research involves Indigenous individuals, describe your community engagement plan (see TCPS-2 Articles 9.1 to 9.6). Supply all relevant documents including supporting letters, research agreements, etc. If community engagement will not be sought, explain why the research does not need it, referencing TCPS-2 Article 9.2. (5,000)	

3. Research Methods and Information Source

#	Question	Answer
3.1	Provide the research topic and purpose of the proposed research. (2,000)	
3.2	Literature Review: provide a brief critical summary of the relevant research literature. (7,500)	
3.3	Reference List (7,500)	
3.4	Describe the original/source data collection. Describe how and why the data were originally gathered, when, from whom and by whom. If the data or materials were collected for research purposes, how were participants recruited? (7,500)	
3.5	Describe how the purpose of the current research builds on, and/or differs from, the purpose for which the information (data/records) was originally gathered. (7,500)	
3.6	Who is the steward/custodian of the source data collection? (400)	
3.7	Has your proposed research been approved by the steward/custodian(s) of the records/data? If yes, provide the date and attach permission and/or letters from the data steward/custodians. If no, please provide an anticipated date of approval or explain why approval could not be granted prior to submission of this REB application. (1,000)	
3.8	Please describe how the findings will be disseminated to the academic community. Will the findings be disseminated to any other stakeholder groups (e.g., participants, organizations)? If so, please describe the process of dissemination among each of the relevant groups. (2,500)	

4. Participants and Informed Consent

#	Question	Answer
4.1	For the current analysis, describe and justify the sample or sub-sample being used (e.g., number of participants, inclusion/exclusion criteria, etc.). Explain the process of identifying, selecting and obtaining records from the collection. (5,000)	
4.2	If data were originally collected for research purposes, how was informed consent originally obtained from participants? Indicate the information uses for which participants originally gave consent. To what extent does the original consent address the purposes of the current study? Attach the original invitation to participate/consent form if available. (5,000)	
4.3	Will consent be obtained from individuals prior to using data? If yes, explain the informed consent process in detail and append invitation to participate and consent form(s). If no, explain why this would be impossible or impracticable, and why it is unlikely to adversely affect the welfare of individuals to whom the information relates (referring to each of the criteria described in TCPS2 (2022) 5.5A or 5.5B and/or 12.3A or B). (5,000)	
4.4	Is there a relationship (for example, supervisory, teacher/student/child) between you and the participants in the sample?	

4.5	If Yes, what is the nature of that relationship? Does it involve a difference in power (e.g., do any of the participants report to you, or are you involved with decisions affecting their careers)? (2,000)	
4.6	Indicate any possible conflicts of interest or other ethical difficulties that could exist or arise as a consequence of the nature of the sample, and describe the steps you will take to overcome such problems. (2,500)	

5. Additional Information

#	Question	Answer
5.1	Briefly discuss the data to be captured from the original/source data collection, the data fields to be used, or the variables to be used for the proposed analyses. Provide the rationale for the use of the information being captured. Append any available data capture sheet (e.g., field data collection template, score card, survey questions, etc.) for record review, or list of variables to be used. (2,500)	
5.2	Briefly describe the data analysis plan. Indicate how the proposed data analyses address the study's primary objectives or research questions. (2,500)	
5.3	Potential Benefits: Please describe the benefits associated with the research for the participants, a specific group within society, or society as a whole. Please describe / explain in as much detail as possible. (2,000)	
5.4	Costs for Participants: Are there any potential costs to the original participants? Costs may be psychological/ emotional (including feeling uncomfortable, embarrassed, anxious, or upset), or social (including possible loss of status, privacy, or reputation). Other costs may involve data security (i.e., risk to participant from data exposure). (2,500)	
5.5	If yes to 5.4 (there are "costs" to participants), will you have systems or supports in place to assist participants who become distressed due to study participation? If so, please describe these completely. (2,500)	
5.6	If applicable, describe how participants will be informed of any material incidental findings – a discovery about a participant made in the course of research (screening or data collection) that is outside the objectives of the study that has implications for participant welfare (health, psychological or social). See TCPS 2 (2022) Article 3.3. (2,500)	
5.7	Distribution of Findings to Participants: Do you intend to make the results of your research available to those who participated in your study? If yes, please describe how you will make the findings available. (2,500)	

6. Confidentiality, Anonymity, Data Retention

#	Question	Answer
6.1	Describe the role and duties of all research team members (including students, research assistants, and supervisors) in relation to the extracted data. (1,500)	
6.2	What is the level of participant identifiability in the original/source data? Select one.	Anonymous Anonymized De-identified/coded Identifying

6.3	Who will access the source data to extract the data for this research? Explain their role or qualifications. If there is identifying information in the source data, how will the privacy of individuals whose data/samples are stored in the collection be protected during this data access? (2,500)	
6.4	Indicate the level of identifiability of the data that will be extracted from the source data collection for use in this research. It is best practice to collect data at the lowest level of identifiability possible to meet study objectives. Select one.	Anonymous Anonymized De-identified/coded Identifying
6.5	Describe measures to ensure privacy and confidentiality of study documents and participant data during the data collection and analysis phase. [Note that plans for long term storage are be covered in Question 6.9.] (5,000)	
6.6	Research using health information may be subject to Nova Scotia's Personal Health Information Act. In accordance with this Act, if personal health information will be used please explain why the research cannot reasonably be accomplished without this information. (2,500)	
6.7	Will there be any linking of separate data sets as part of this research? If yes: a) Why is this linkage necessary? B) Describe how the linkage will be conducted (it is helpful to append a flow diagram). C) Does this linkage increase the identifiability of the participants? If so, describe reasonably foreseeable risks to privacy and how these will be mitigated. (2,500)	
6.8	Data security during the study: 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. In particular, indicate the steps that will be taken to protect the security of any directly or indirectly identifiable information, especially if it is shared with others. Include physical security and technological security. If there are codes to be used that link data to information that could identify participants (names, addresses, etc.), security of these codes should be described. (2,500)	
6.9	Data security during long term storage: Describe plans for data retention and long-term storage (i.e., how long data will be retained, in what form and where). Will the data eventually be destroyed or irreversibly anonymized? If so, what procedures will be used for this? Discuss any plans for future use of the data or materials beyond the study currently being reviewed. (2,500)	
6.10	Do you intend to deposit the data in repository (e.g., open access repository, archive) for future unspecified use? If applicable, identify and describe the data repository in which the research data will be deposited. What is its focus, who are its target users, who can access deposited data and under what circumstances? For how long will the data be kept in the repository? Please note that the REB may ask for additional information about the repository. (2,500)	
6.11	If applicable, describe the data set to be released to the repository. If there is personal and/or sensitive information in the data, describe how you will prepare the data for submission to the repository and mitigate risks to privacy. (2,500)	

6.12	Is agreeing to have one's data deposited a requirement for participation in the study? If yes, provide a justification. If no, indicate how participants can opt in or out. (2,500)	
6.13	Will you be using any electronic tool (e.g. survey company, software, data repository) to help you collect, manage, store, share, or analyze personally identifiable data that makes the data accessible from outside Canada? Describe. (2,500)	
6.14	Will any information that may reasonably be expected to identify an individual (alone or in combination with other available information) be accessible outside Canada? Describe. (2,500)	
6.15	Is there information critical to your study that has not been described or discussed elsewhere / in any other section? (2,500)	

7. Funded Research

#	Question	Answer
7.1	Is your research being funded or financially supported?	
7.2	If Yes, provide the sponsor/agency/funder name and program.	
7.3	What is the EXACT title of the project associated with the funding application? (500)	
7.4	Name of Principal Investigator for whom the award was granted (if not yourself).	
7.5	Date when the funding was granted?	

8. Supporting Material and Documents

#	Question	Answer
8.1	Which of the following consent-related forms and materials are included in your file attachments?	Invitation to Participate (original and/or new, as applicable) Consent Form(s)/Assent Form(s) (original and/or new as applicable) Community Engagement Plan None / not applicable
8.2	Which of the following instruments are included in your file attachments?	Data capture sheet/list of data fields, variables/ survey items Interview / focus group guide(s) Surveys / questionnaires Other test instruments None / not applicable
8.3	Which of the following analysis materials are included in your file attachments?	Flow diagram outlining data collection and linkages None / not applicable

8.4	Which of the following external permissions and approvals have been included in your file attachments?	Steward/custodian permission letters, support/cooperation correspondence Research agreements (required for research involving Indigenous communities REB approval from other institutions None / not applicable
8.5	Which of the following research team agreements have been included in your file attachments?	Research assistant confidentiality agreement None / not applicable
8.6	What other documents have been included in your file attachments?	TCPS-2 CORE 2022 Certificate(s) for StFX affiliated principal investigators and co-investigators and any other research team members who have completed CORE 2022 Any other documents not listed above None / not applicable
8.7	If any other documents have been included, list them here.	