

**STFX Research Ethics Board (REB) Application Template**

**Do NOT submit this form, you must submit using the** [**ROMEO portal**](https://www.stfx.ca/research/romeo-researcher-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.

**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 must provide the University's Research Ethics Board (REB) with this completed application before conducting any research involving human participants, whether the research takes place on campus or elsewhere.

All StFX affiliated applicants who are principal investigators, co-investigators, and supervisors 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](http://http:/www2.mystfx.ca/research-ethics-board/submission-deadlines) 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**](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html).  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**](https://www.mystfx.ca/sites/research-ethics-board/files/2021-05/Guidelines%20for%20Invitation%20Consent%20and%20Assent%20Forms%20March%2025%202020%20%281%29%20%281%29.docx).
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, 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 supporting documents through the [**ROMEO system**](https://www.stfx.ca/research/romeo-researcher-portal) 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 is reviewed at the departmental level by departmental Research Ethics Committees, [**using the form found here**](https://www.mystfx.ca/research-ethics-board/sites/research-ethics-board/files/2021-09/STFX%20REB%20Application%20Form%20-%20Undergraduate%20Students%20-%20updated%20%28002%29_5.docx).

 d. **Course-Based Research**: is reviewed at the departmental level by departmental Research Ethics Committees, [**using the course-based research form found here**](https://www.stfx.ca/research/research-ethics-board/forms-templates).

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**

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| **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**

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| **#** | **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**

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| **#** | **Question** | **Answer** |
| 3.1  | Provide the research topic. (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 design of the study including a description of the research methodology. (7,500) |  |
| 3.5  | Detail the research methods to be used and provide a rationale for the use of these methods. (15,000) |  |
| 3.6  | 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. (5,000) |  |

**4. Participants**

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| **#** | **Question** | **Answer** |
| 4.1  | Describe the participant population; who will the participants be? (2,000) |  |
| 4.2  | What is the approximate number of participants? (1,500) |  |
| 4.3  | How large a group will the participants be selected from? (1,500) |  |
| 4.4  | How will your participants be selected? (2,500) |  |
| 4.5  | Provide specific details about the recruitment process. (7,500) |  |
| 4.6  | Is there a relationship (for example, supervisory, teacher/student/child) between you and the participants in your study? |  |
| 4.7  | 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) |  |
| 4.8  | Indicate any possible conflicts of interest or other ethical difficulties that could exist or arise as a consequence of the nature of the proposed participants, and describe the steps you will take to overcome such problems. (2,500) |  |
| 4.9  | Describe the informed consent process: A) How, when and by whom will the study information be conveyed to prospective participants? B) How will the researcher ensure prospective participants are fully informed? C) Describe whether and how you will obtain informed consent (e.g., written signature, audio-recorded, verbal agreement, implied consent for low risk studies etc.). (2,500) |  |
| 4.10  | How will you make sure that participants know their involvement is voluntary? (2,500) |  |
| 4.11  | Discuss how participants will be given the opportunity to withdraw their participation (and/or their data) and any time (or content) limitations on this. If participants will not have opportunity to withdraw their participation and/or their data explain why. (2,500) |  |
| 4.12  | Is the research to be carried out within an organizational setting such as a school board, government department, or private company?  |  |
| 4.13  | If Yes, provide a copy of your letter requesting permission to carry out the research in this setting or provide any explanation for the REB of why such approval will not be sought. (2,000) |  |
| 4.14  | If you do not intend to use an Invitation to Participate Form, how will the nature and purpose of the research be explained to the participants? (2,000) |  |
| 4.15  | Transcriptions of Interviews or of Group Discussions: If transcription is necessary, who will do the transcription? (2,000) |  |

**5. Additional Information**

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| **#** | **Question** | **Answer** |
| 5.1  | Plain Language Usage: What is the estimated literacy or grade level of your participants? (2,000) |  |
| 5.2  | If there is reason to believe that reading comprehension could be an issue, explain your reasons for believing that the information provided will be readily understood by the target population. Provide a Flesch-Kincaid score of your participant documents. (2,000) |  |
| 5.3  | Deception: Does your research involve deception?  |  |
| 5.4  | If Yes, explain why it is necessary for your research and how it will be explained to the participants that deception has been involved. Please describe the procedure for obtaining post-debriefing consent. (2,000) |  |
| 5.5  | Describe any financial or other incentives that will be offered to participants (for example, everyone gets a gift card or a "gift"; they will be entered into a draw for prizes; they will receive academic credit, etc.). Describe whether or not participants who start but do not complete the study will also receive any or all of the incentives given to those who do complete the study. How will this be handled? (5,000) |  |
| 5.6  | Discuss any expenses participants are likely to incur in order to participate and whether/how these will be reimbursed. (2,500) |  |
| 5.7  | Potential Benefits: Please describe the benefits associated with the research for the participant. Also describe the benefits to either a specific group within society, or society as a whole. Please describe / explain in as much detail as possible. (2,000) |  |
| 5.8  | Costs for Participants: For research where there are potential costs - physical, psychological, or social - for the participants other than those of time or effort, please describe. Costs may be physical (including bodily contact, administration of a substance, fatigue/exhaustion), psychological/ emotional (including feeling uncomfortable, embarrassed, anxious, or upset), social (including possible loss of status, privacy, or reputation). Other costs may involve data security (i.e., risk to participant from data exposure) or be tied to deception. (2,500) |  |
| 5.9  | If yes to 5.8 (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) |  |
| 5.10  | 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 results available. (2,500) |  |

**6. Confidentiality, Anonymity, Data Retention**

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| **#** | **Question** | **Answer** |
| 6.1  | List the name and positions of all team members (and any research assistants) who will have knowledge of participants’ identities. (1,500) |  |
| 6.2  | What is the level of participant identifiability in the study data?  | AnonymousAnonymizedDe-identified/codedIdentifying |
| 6.3  | Specify which members of the research team (or others, such as research assistants) will have access to participants’ data and for what purpose. (1,500) |  |
| 6.4  | 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) |  |
| 6.5  | How will participant confidentiality be protected when quantitative research results (study data) are reported?  | Only aggregate data will be presentedIndividual de-identified, anonymized or anonymous data will be presentedOther (describe below)Participant confidentiality will not be protected in the research resultsNot applicable (no quantitative data) |
| 6.6  | If “other”, briefly describe dissemination plans with regard to identifiability of quantitative data. (1,500) |  |
| 6.7  | How will participant confidentiality be protected when qualitative research results (study data) are reported? | Only aggregate data will be presentedIndividual de-identified, anonymized or anonymous data will be presentedOther (describe below)Participant confidentiality will not be protected in the research resultsNot applicable (no qualitative data) |
| 6.8  | If “other”, briefly describe dissemination plans with regard to identifiability of qualitative data. (1,500) |  |
| 6.9  | 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. Will there be identifying, personal, and/or sensitive information in the data? Please describe how you will prepare the data for submission to the repository and mitigate risks to privacy(2,500) |  |
| 6.12 | If it is your intention to deposit anonymous or anonymized data, please describe how you will remove directly identifying data. Please also consider and describe how you will remove quasi-identifiable data or combinations of data (e.g., combinations of responses to demographic items) that may result in individual participants being identified. (2,500) Please see the following for more information: [*https://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1109&context=wlpres*](https://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1109&context=wlpres) |  |
| 6.13 | 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) |  |
| 6.14  | Will you be using any electronic tool (e.g. survey company, software, data repository) to help you collect, manage, store, share, or analyze data that makes the data accessible from outside Canada? Describe. (2,500) |  |
| 6.15  | 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) |  |
| 6.16 | 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) |  |
| 6.17  | Is there information critical to your study that has not been described or discussed elsewhere / in any other section? (2,500) |  |

**7. Program Review | Evaluation**

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| **#** | **Question** | **Answer** |
| 7.1  | Does your research involve the review of an existing program?  |  |
| 7.2  | If your application involves program review or an examination of quality assurance, please indicate for the REB your reasons for believing that the research requires ethical review. (2,000) |  |
| 7.3  | Will the results of this evaluation study be made available to the research community?  |  |
| 7.4  | If Yes, how will this be completed? (2,000) |  |

**8. Funded Research**

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| **#** | **Question** | **Answer** |
| 8.1  | Is your research being funded or financially supported?  |  |
| 8.2  | If Yes, provide the sponsor/agency/funder name and program. |  |
| 8.3  | What is the EXACT title of the project associated with the funding application? (500) |  |
| 8.4  | Name of Principal Investigator for whom the award was granted (if not yourself). |  |
| 8.5  | Date when the funding was granted? |  |

**9. Support Material and Documents**

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| **#** | **Question** | **Answer** |
| 9.1  | Which of the following consent-related forms and materials are included in your file attachments? | Invitation to ParticipateConsent Form(s)|Assent Form(s)Community Engagement PlanAny scripts to be used to in the procedureNone / not applicable |
| 9.2  | Which of the following test instruments are included in your file attachments? | Interview / focus group guide(s)Surveys / questionnairesOther test instrumentsNone / not applicable |
| 9.3  | Which of the following recruitment-related materials are included in your file attachments? | Recruitment ad(s) / poster(s)None / not applicable |
| 9.4  | Which of the following debriefing materials are included in your file attachments? | Debriefing formPost-debriefing consent form(s) |
| 9.5  | Which of the following external permissions and approvals have been included in your file attachments? | Letter(s) seeking permission from organizations &/or institutionsReceived permission letter(s) from organizations &/or institutionsREB approval from other institutionsNone / not applicable |
| 9.6  | Which of the following research team agreements have been included in your file attachments? | Research assistant confidentiality agreementTranscriptionist confidentiality agreementNone / not applicable |
| 9.7  | 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 2022Any other documents not listed aboveNone / not applicable |
| 9.8  | If any other documents have been included, list them here. |  |

**List the titles of all documents / files attached, grouped as a single PDF (such as Consent Form, Survey, Recruitment Poster).**

**\*\*A signature from the Chair of the Departmental or Program Research Ethics Committee (REC) is required once the application has been approved and before it is submitted to the University REB through Romeo\*\***

**REC Chair’s name (Printed)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**REC Chair’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date Approved\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**