Saint Mary's University

FOR OFFICE USE ONLY
SMU REB #:
DATE RECEIVED:

RESEARCH ETHICS BOARD
APPLICATION FOR ETHICS REVIEW OF RESEARCH INVOLVING HUMANS

Form 1: Student/Faculty/Staff

SUBMISSION CRITERIA FOR INITIAL REB REVIEW — Direct to: ethics@smu. ca

Proposals must meet the criteria for REB review work to begin:

1. The latest version from the REB website must be filled. Use Form 1C if the research holds current clearance from another Canadian REB.
2. All Form 1 fields demonstrating details about the research are completed (no field appears blank, "n/a" is inserted when applicable);
3. All materials requiring REB review are attached. Consider submitting a total of 2 attachments: 1. Form 1, and 2. All research materials.
4. All SMU affiliated parties, including the Faculty Supervisor for student research, provided a written (not generated) signature on Form 1;
5. For student research, applications are sent by the Faculty Supervisor. For faculty or staff research, applications are sent by the Faculty or Staff Principal Investigator.

TECHNICAL INSTRUCTIONS- Open the form using Adobe Reader. — Contact: sas@smu.ca

For technical assistance while working with the forms please contact the Software Application Support Centre (SAS) at sas@smu.ca. The SAS can assist SMU users with resolving their technical issues. The REB forms are regular Adobe fillable, savable, PDF forms – this way work can be saved in stages and returned to during preparation stages- forms must be opened with Adobe Acrobat Reader to ensure that they look and function correctly. Tip from the SAS Lab: To correctly work with the form: 1. Right-click on the form, 2. Select "Open With", 3. Select "Adobe Acrobat Reader". For stations that are not serviced by SMU, a free non-tial version is available at: https://get.adobe.com/reader/?_branch_match_id=860199318184484959. Once signed, this form will lock. Save a copy to edit.

LISTING OF MATERIALS ENCLOSED FOR REB REVIEW

EXTERNAL CLEARANCE MATERIALS	Yes	n/a
Clearance from external university/school/hospital/agency, REB body (when applicable)	○	○
Clearance from individual/organization/department (when applicable)	○	○
Clearance from government for international research (when applicable)	○	○
TCPS 2: Course on Research Ethics (CORE) Certificate(s) of Completion (when applicable)	○	○
RECRUITMENT MATERIALS		
Proposed recruitment letter/script/email (required)	☐	
Proposed advertisement script/poster (when applicable)	○	○
RESEARCH INSTRUMENTS		
Proposed screening, demographic/survey/focus group guide/audiotory/visual stimuli/other (when applicable)	○	○
Proposed individual/group/focus group interview plans(s)/supplementary tables or figures (when applicable)	○	○
Proposed individual/group/focus group interview questions (when applicable)	○	○
INFORMED CONSENT MATERIALS		
Proposed Informed Consent Form(s)/Script(s) for research participant (required)	☐	
Proposed Information Letter(s) for research participant (when applicable)	○	○
Proposed Information Letter(s) for research participant's parent/guardian/proxy (when applicable)	○	○
Proposed Informed Consent Form(s)/Script(s) for research participant's parent/guardian/proxy (when applicable)	○	○
FEEDBACK/DEBRIEFING MATERIALS		
Proposed feedback letter(s)/script(s) to research participant (when applicable)	○	○
Proposed feedback letter(s)/script(s) to research participant's parent/guardian/proxy (when applicable)	○	○
Proposed debriefing letter(s)/script(s) to research participant (when applicable)	○	○
Proposed debriefing letter(s)/script(s) to research participant's parent/guardian/proxy (when applicable)	○	○

LISTING OF ADDITIONAL PROPOSAL SPECIFIC MATERIALS ENCLOSED FOR REB REVIEW

Itemize other research materials involved in the proposal requiring REB review, not yet listed:

1.

2.

3.

4.

5.

ADDITIONAL INFORMATION RELATING TO THE MATERIALS ENCLOSED FOR REB REVIEW

TYPE OF APPLICATION FOR REB REVIEW

Check the type of application.

Option 1:

◯ *Student research - submitted by Faculty Supervisor*

Option 2:

◯ *Faculty/Staff research- submitted by Faculty or Staff Principal Investigator*

REGISTRATION CRITERIA FOR REB REVIEW CHECKLIST (verify listings by checking each)

1. All Form 1 fields are completed. Fields do not appear blank. "N/a" is indicated when applicable. ☐
2. All materials requiring REB review are attached. (Consider combining and submiting in 1 document.) ☐

   All materials are attached in PDF or Word format without the use of folders. Ensure you name the document something that reflects what the document is and matching exactly how they are referenced in the methods section of Form 1. I.e., "Informed Consent Form- Group 1", "Recruitment Email- Group 3" or "Interview Questions - Group 1 of 4". Avoid using slang, student names, "clean", "final", "draft" in the document name. Consider combining all materials in 1 document.
3. All SMU affliliated parties, including the Faculty Supervisor for student research, have signed Form 1. ☐
4. Application is directed to ethics@smu.ca. For student research, application is sent by the Faculty Supervisor. For Staff and Faculty research, application is sent by the Principal Investigator. ☐

SECTION A

EXTERNAL CLEARANCE

Is additional organizational, institutional, governmental or other permission needed to conduct the research? (I.e., Other University, School Board, Hospital, Agency, Police, Navy, First Nations, Inuit, Metis, community group, data holder agreement, letter of support, etc. permission needed prior to accessing individuals or their data? If yes, please explain.

◯ Yes ◯ No

MULTI-JURISDICTIONAL RESEARCH

1. Will research be conducted outside of Saint Mary's University? ◯ Yes ◯ No

TCPS 2, Chapter 8. B: Ethics Review of Research Conducted Outside the Institution:
When conducting research outside the home institution, whether in Canada or abroad, researchers shall provide their home REBs with the following considerations:

a) Relevant information about the rules governing research involving humans and the ethics review requirements at the research site:

b) The names and contact information for the relevant REB or comparable ethics bodies at the research site:

c) Relevant information/norms about the participants and their circumstances that might have a bearing on the research ethics review by the researcher's home REB. Demonstrate any elements important when considering the appropriateness of recruitment strategies, languages spoken, local factors affecting the informed consent process and how they will be addressed (i.e., a request from a visitor to sign documents would be treated with suspicion based on customs, previous history, etc.) effective mechanism for returning of research results and realistic strategies for achieving contact between one another during and after the research involvement, etc.

SCHOLARLY REVIEW

Please describe any scholarly review that has been applied to this proposed research that the REB should consider. I.e., The research may have received internal review (i.e., department, thesis committee, etc.) or external review (i.e., Tri-Agency, funding source, other academic or institutional, etc.)

☐ N/A

INTERNAL CLEARANCE

Is additional individual/organizational/departmental permission needed to conduct the research? (I.e., Permission from an individual, department head, to perform recruitment strategies, use of resources, services, data, etc.) If yes, please explain and provide a Letter of Support, when applicable.

☐ N/A

Note from the Faculty of Graduate Studies and Research: "Graduate student researchers are required to obtain clearance from the Faculty of Graduate Studies and Research via the Graduate Research Hazards Assessment (GRHA) process where applicable, as per university regulations." (The GRHA clearance document does not need to be submitted to the REB and is a separate process from REB review. For more information and to obtain the required clearance, please contact the Faculty of Graduate Studies and Research Office and see the procedures involving the required GRHA Form.) The clearance is provided by the Dean of Research.

SECONDARY USE OF DATA

Does your project involve secondary use of data collected for other purposes than originally intended/consented to? (I.e., data that has been collected from human participants for other than the current purpose.) If so, please detail.

◯ Yes ◯ No

CONFLICTS OF INTEREST

Does the proposed research involve real, potential or perceived conflict of interest as a result of or in connection to this study? (I.e., Your or your team's judgment may be influenced or appear to be influenced by private or personal interests such as renumeration, intellectual property rights, rights of employment, consultancies, board membership, stock options, commercial interests, etc.) If so, please identify and disclose to research participants any conflicts and explain the extend of the researcher's involvement.

Be sure to address the presence of any real, potential or perceived conflict of interest on the part of the researchers, their institutions or the research sponsor(s) and disclose the nature of the confict if a researcher is acting in a dual role to potential research participants during the informed consent process (via the Informed Consent Form/Script).

◯ Yes ◯ No

SECTION B

TYPE OF APPLICATION

1. Type of Application: ◯ Faculty ◯ Student ◯ Staff

2. Type of Research: Choose one

3. Title of the Research:

a) Enter the complete research title.

b) Enter the complete research title for public release (when different from above). Enter "n/a" when not applicable.

Important! All active research studies are listed on the SMU REB website.

4. (a) Select anticipated start date:

Note: Recruitment of research participants is considered as the start date of the study.

(b) Select anticipated end date:

Note: The research is considered completed when no further recruitment and data is anticipated to be collected from research participants and all data is collected, handled and stored in accordance with the provisions of the latest REB clearance.

PRINCIPAL INVESTIGATOR ASSIGNMENT OF INVESTIGATOR ROLES AND LIST OF CONTACTS

It is important that the assignments and contacts for the full research team are preseted clearly:
Student research: List the Faculty Supervisor first. List the institutional status as it relates to SMU.
Faculty/Staff research: List the Principal Investigator first.
Multi-jurisdictional research: List the Local (SMU or NSCAD) Principal Investigator first.

5.(a) Role: Choose one

Name:

Institution: Choose one

Institutional Status: Choose one

Department:

Phone #:

Alternate Phone #:

Email:

Alternate Email:

(b) Role: Choose one

Name:

Institution: Choose one

Institutional Status: Choose one

Department:

Phone #:

Alternate Phone #:

Email:

Alternate Email:

(c) Role: Choose one

Name:

Institution: Choose one

Institutional Status: Choose one

Department:

Phone #:

Alternate Phone #:

Email:

Alternate Email:

(d) Role: Choose one

Name:

Institution: Choose one

Institutional Status: Choose one

Department:

Phone #:

Alternate Phone #:

Email:

Alternate Email:

(e) Role: Choose one

Name:

Institution: Choose one

Institutional Status: Choose one

Department:

Phone #:

Alternate Phone #:

Email:

Alternate Email:

Please list all additional research team members at the "Additional Information" Section K, at the end of the form.

RESEARCH FUNDING

6.(a) Funding status: ◯ Funded ◯ Funding pending ◉ Unfunded

(b) Tri-Council Agency: ☐ SSHRC ☐ NSERC ☐ CIHR ☐ Not Tri-Agency funded

(c) Internal (Specify): ☐

(d) Other (Specify): ☐

(e) Grant Number:

(f) Grant Name:

(g) Funding Period: From: (dd/mmm/yyyy) To: (dd/mmm/yyyy)

(h) Grant title of the research:

* All funding fields are required. The REB reports the provided information to the University Grants Officer, required to release research funds, once research ethics clearance is obtained. Any changes to funding must be promptly reported to the REB throughout the life cycle of the research.

SECTION C

PILOT STUDY (when applicable)

1. Pilot studies, involving the collection of data from any human participant, are meant to inform recruitment, study duration, the calibration of equipment or materials, and other methodological facets of a main study. Collecting any pilot data falls within the definition of research requiring REB review (see Article 2.1, TCPS 2). If you intend to conduct a pilot study, please provide the REB with the following information:

(i) the goal of the pilot study;
(ii) a justification for the sample size of the pilot study;
(iii) a description of who and how you will recruit for the pilot study;
(iv) a full description of the methods for the pilot study;
(v) an account on how the outcome of the pilot study will inform the main study; and
(vi) plans to disseminate the findings from the pilot study (if applicable).

Include a copy of any pilot study materials in this application you intend to use for the pilot study that may be different from the main study (e.g., recruitment script, informed consent, specialized measures, etc.)

If you wish to include more information, use "Section K- Additional Information", at the end of the form.

MAIN STUDY

1. Purpose and Rationale:
Describe the proposed research project in non-technical language. The REB is composed of members drawn from across various academic disciplines and members of the general public; therefore, in plain and clear language, describe the purpose and objectives of the study and any hypotheses to be investigated. (I.e., Why is this study being done?) If available, please include references to similar research in the area.

If you wish to include more information, use "Section K- Additional Information", at the end of the form.

2. Methods:

Describe in some detail all types of procedures and methods to be used in the main study. (I.e., how are you doing it?) Provide a sequential description of what the participants will be invited to do in the study and what information will be obtained from them. Describe and attach a copy of all materials to be used in the study such as reference measures or scripts of interview questions. In more methodologically complex research a figure, table, or a timeline may be helpful or needed for easier comprehension. Please avoid acronyms and jargon. Of the study instruments being used, clarify which ones are not standardized instruments.

If you wish to incude more information, use "Section K- Additional Information" at the end of the form.

DECEPTION

1. Does this study involve any deception or withholding of key information? If so, describe the details of the deception and justification for its use.

◯ Yes ◯ No

2. Will information be withheld from participants that might reasonably lead them to decline to participate in the study? If yes, please explain below.

◯ Yes ◯ No

3. Will the participants be video or audio taped without their knowledge or consent?

◯ Yes ◯ No

4. Please outline the process to be used to debrief participants about why deception was used. Append a copy of the debriefing sheet.

☐ N/A

SECTION D

FAIRNESS AND EQUITY IN RESEARCH PARTICIPATION

1. Research participants: (Check all that apply and note the availability of custom text.)

- ☐ SMU Undergraduate Students
- ☐ SMU Graduate Students
- ☐ SMU Faculty
- ☐ SMU Staff
- ☐ Adolescents
- ☐ Adults
- ☐ Seniors
- ☐ Members of Isolated Communities
- ☐ (Enter custom text)

- ☐ Minors
- ☐ Pre-school Students
- ☐ Primary-school Students
- ☐ High School Students
- ☐ College Students
- ☐ First Nations
- ☐ Inuit
- ☐ Metis
- ☐ (Enter custom text)

- ☐ Incarcerated
- ☐ Institutionalized
- ☐ Care Facility
- ☐ Illiterate
- ☐ Non-english speaking
- ☐ Employees
- ☐ Employers
- ☐ Officials
- ☐ (Enter custom text)

Note: Research involvng children, the elderly, seniors, people with disabilities or other vulnerable groups may require a Vulnerable Sector and/or Child Abuse Registry clearance.

2. What is the anticipated number of participants and/or what will be the rationale/decision making framework for ending sampling?

3. Please specify any other distinguishing characteristics of the participants (e.g., gender, ethnicity, etc.)

4. Specify the age range of the participants. Lower age limit: Upper age limit:

Consult the REB's Age of Consent guidelines, when needed. Lower and upper age limits need to be provided for REB review.

5. Specify the exclusion criteria: a) Identify any exclusion criteria, and b) justify the exclusion criteria by explaining the rationale for the criteria that appears to violate the principle of inclusiveness (i.e., lower and upper age limits, exclusion of persons based on age, gender, departmental affiliation, employment status, etc.)

6. a) Which linguistic groups will be recuited?

☐ English-speaking ☐ French-speaking ☐ Other: *Enter custom text*

b) Is translation required? ◯ Yes If yes, please detail below. ◯ No ◯ Unaware at this time

c) Is a translator required? ◯ Yes If yes, please detail below. ◯ No ◯ Unaware at this time

d) Given the study sample, is it likely that participants may have communication difficulties (e.g., who may need translation, are illiterate, may have trouble understanding or producting speech or who may require special support)? If yes, please detail.

7. Is there any pre-existing relationship between the researcher(s) and the researched? (e.g., Instructor-student, Manager-employee, Minister-congregant.) If yes, please explain. ◯ Yes ◯ No

8. Is the researcher, associate or research assistant in a direct position of power in relation to the participants outside the scope of the research study? If yes, please explain. ◯ Yes ◯ No

RECRUITMENT

1. Where will the study take place?

- ☐ SMU Campus Building: Room #:
- ☐ Off Campus HRM
- ☐ Outside HRM NS
- ☐ Out of Province
- ☐ Outside of Canada
- ☐ Online

2. List the names of all research team members who will be recruiting research participants.

3. How will interested participants be able to let the investigators know that they wish to participate in the research? List the recruitment method being used. I.e., posters, newspaper, radio, telephone script, email, script, website, social media, video recording, database (e.g. SONA), third party company, survey panel (Mechanical Turk) snowball sampling or other methods and detail how they will be distributed.

4.(a) Append a copy of all recruiment materials (posters, advertisements, flyers, letters, email text, telephone scripts, adverstisement intended for social media, etc.) to the application.

(b) Verify, by checking below, that all recruitment materials include all of the below noted minimum requirements for inclusion in adverstisement:

SMU REB File Number (Provided at registration with the REB)

- ☐ Title of the study
- ☐ Name and contact of investigators and the research facility
- ☐ Sponsor/funder of the study (when applicable)
- ☐ Purpose of the study
- ☐ Study site location (including online)
- ☐ Eligibility criteria
- ☐ Time commitment
- ☐ Compensation (optional)

SECTION E

POTENTIAL BENEFITS

1. Identify any known or anticipated direct and/or indirect benefit (not compensation) of the research. If any, state the potential benefit(s) on the Informed Consent Letter/Script.) Newly recognized benefits can be communicated during the ongoing consenting process throughout the life cycle of the research.

(a) Are there potential direct benefit(s) to participants? ◯ Yes ◯ No

(b) Are there potential indirect benefit(s) to participants? ◯ Yes ◯ No

(c) Are there potential benefit(s) to the participant's community? ◯ Yes ◯ No

(d) Are there potential benefit(s) to the scientific/scholarly community and/or society? ◯ Yes ◯ No

SECTION F

FORSEEABLE RISKS

Minimal risk research: "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 the aspects of their everyday life that relate to the research." (TCPS 2, Ch.2, B.).

Consider both individual as well as group vulnerabilities.

1. Type of research: ◯ Minimal Risk ◯ Exceeds minimal risk

2. Are any of the following categories of risks foreseeable?

(a) Physical risk (e.g., bodily contact, administration of any substance, physical discomfort, tiredness) ◯ Yes ◯ No

(b) Psychological or emotional risk (e.g., feeling uncomfortable, embarrassed, worried, anxious or upset) ◯ Yes ◯ No

(c) Social risk (including possible loss of status, privacy and/or reputation) ◯ Yes ◯ No

(d) Legal risk (e.g., potential of apprehension, arrest, being identified as a member of a legally compromised group, being sued) ◯ Yes ◯ No

(e) Economic risk (e.g., loss of income, incurred expenses) ◯ Yes ◯ No

(f) Will all reasonable precautions be taken to protect the health and safety of participants? ◯ Yes ◯ No

(g) Will your methods induce participants to act against their wishes? ◯ Yes ◯ No

(h) Will participants be asked to disclose information that is intimate or sensitive? ◯ Yes ◯ No

3. If "yes" was indicated in Question 2, explain the risks that are foreseeable:

4. Is there a foreseeable likelihood that, in the course of this research, you will acquire information that is legally required to be reported (for example, abuse or neglect of a child, reports of harm to self or others, etc.)? Confirm that you have investigated your duty to report and details the associated plans.

MANAGEMENT OF FORESEEABLE RISKS

1. Describe how the foreseeable risks will be minimized and harms that participants may experience handled.

2. List the resources you will make available to research participants who might experience unanticipated issues/adverse events stemming from participation in the research.

SECTION G

PRIVACY AND CONFIDENTIALITY

Note: Anonymity of participants and/or confidentiality of data are often laudable goals but it is not always possible or appropriate in all types of research. In fact, there are limits to confidentiality as described in the TCPS 2; in some traditions, these notions are considered inappropriate. Consider whether this is a desirable goal and, if so, the extent to which your methods allow you to keep the promises being made. Ensure that the consent process includes an accurate description of these concepts and the ability of your study to fulfill any promises to participants. Consider the use of pseudonyms and/or linkages, labels, generic aggregates, (Example: "a small town in northern Newfoundland") and consider who may access the data.

Personal Information defined: Freedom of Information and Protection of Privacy Act, 1993, c.5, s. 1., 3 (1), i.(i.-ix), "identifiable information": http://nslegislature.ca/legc/statutes/freedom.htm

1.(a) Will personally identifying information be collected (directly or indirectly)? If yes, please detail what will be collected and justify the collection of each item for the purposes of this research question. ◯ Yes ◯ No

(b) Where the research involves extraction or collection of personally identifiable information, please describe from whom the information will be obtained and what it will include. ☐ N/A

(c) Will personally identifiable information be collected using a server that stores data outside of Canada? If yes, ensure that the consent process includes a disclosure statement of this information. ◯ Yes ◯ No

(d) Will personally identifiable information collected in Nova Scotia be taken or stored outside of Canada? If yes, legislation requires that personally identifiable information 1. must be stored on campus securely, 2. when it is transferred from research site to campus, it be encrypted and sent via secure network (i.e., the SMU Virtual Private Network), and 3. when it is taken (or stored) outside of Canada, mechanism for obtaining explicit consent of individuals be demonstrated. ◯ Yes ◯ No

Related reading: Personal Information International Disclosure Protection Act. 2006, Chapter 3 of the Acts of 2006, amended 2010.

(e) When data is being collected online, what information from its Terms of Use/Service is relevant and will be conveyed to participants during the informed consent process relating to the privacy, confidentiality, transfer and storage of their data? ☐ N/A

2. Describe the procedures you will use to ensure anonymity of participants and confidentiality of data both during the research and in the release of the findings, when applicable. ☐ N/A

SECTION H

DATA MANAGEMENT

If your data deals with sensitive information, describe how the data will be handled in the Informed Consent Form. The TCPS 2 suggestes that judgment should be made using a proportionate risk approach. Thus, the greater the sensitivity of the data, the more researchers must delineate the steps that will be taken to ensure the secure storage of data and to make certain that the security of the data is maintained.

Researchers may choose to implement specific policies with regard to their data and the requirements of their departments but should explain this choice on the application.

If data is stored at the SMU Records Centre, please indicate the details of the agreement as it relates to storage and retention.

1. Detail the procedures you will follow for secure storage of all data, including written records, audio/video tapes, digital media, questionnaires, recordings and computer files.

2. Detail for how long the data will be retained, include the rationale and describe the relating mandates that you are required to follow.

3. Describe the plans involving identifiable data. After the retention period has passed and/or where data needs to be destroyed (e.g. in cases of participant withdrawal), describe the plans for destroying the data. Note that the exact steps for deleting electronic data need to be demonstrated in cases where destruction of the data was promised to research participants. This is to ensure that it meets the technological requirements, meaning i.e., that residual data cannot be pieced back together thereby unauthorized access is prevented.

4. Will it be possible to associate specific information contained in your records with specific participants? ◯ Yes ◯ No

Explain how participants may be identified in the study records and who on the research team is assigned to have access to unique codes identifiying participants.

5. Will information about any individual participants be disclosed to third parties? ◯ Yes ◯ No
(List any restrictions regarding access to disclosure of information, during or at the end of the study, that have been placed on the investigator(s). This includes controls placed by the sponsor, funding body, advisory or steering committee.)

COMPENSATION AND REIMBURSEMENT

1. If the research involves compensating participants or reimbursing for their time or expenses, incentives for participation, entry into a draw, etc. provide details about the amount and type of compensation.

2. How will you handle compensation if participants choose to withdraw from the study? Include breakdown for partial compensation, if relevant.

SECTION I

THE INFORMED CONSENT PROCESS

Significance:

Informed consent is an on-going process that starts with the researcher's first contact with an individual and continues until study completion. Although written consent is a common means of demonstrating and documenting consent, in some research also mandatory by regulators, many disciplines and cultures do not accept written consent as appropriate. In either procedure, researchers shall provide full disclosure about the research so prospective participants can make a fully informed decision about their involvement.

The TCPS 2 reference for the requirements is TCPS 2, Article. 3.2. Consent Shall Be Informed. The official version of the TCPS is the online version at https://ethics.gc.ca/

1. Which of the following forms of consent will be used?

☐ Written- Signed Informed Consent ☐ Implied- Electronic Informed Consent ☐ Oral- Informed Consent Script

2. Draft Informed Consent Form/Script Tool:

To assist with drafting, the requirements, of the TCPS 2, Article 3.2, are listed below. Use this list to verify (a - k) all that have been incorporated in the research.

To understand specific language more closely, the the TCPS provides a "Glossary". In example, to get a better sense of the meaning of "directly" and "indirectly" identifying information (review Glossary: "Information Types").

☐ (a) information that the individual is being invited to participate in a research project;

☐ (b) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;

☐ (c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general , that may arise from research participation;

☐ (d) an assurance that prospective participants:
~ are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
~ will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
~will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

☐ (e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;

☐ (f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;

☐ (g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

☐ (h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
The SMU REB wording for researchers, insert:
"This research has been reviewed and cleared by the Saint Mary's University Research Ethics Board. If you have any questions or concerns about ethical matters, you may contact the the Saint Mary's University Research Ethics Board at ethics@smu.ca or (902) 420-5728."; (The SMU REB # is provided when the proposal is registered with the REB.)

☐ (i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of the participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected and to whom such discolures could be made;

☐ (j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;

☐ (k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.

Please note the SMU REB is suggesting that researchers use participant-friendly language with respect to (k): "By agreeing to participate in this research, I am not giving up any legal rights in the event that I am harmed during the research." This, and other suggestions are listed in the SMU Sample Informed Consent Form- How to Draft an Informed Consent document located on the REB website (under "Forms").

3. In cases where oral consent will be obtained instead of written/signed consent, explain why it is more appropriate to the circumstances and how the individual's consent will be documented.

4. List each research team member who will seek consent?

5. Are there participants who cannot give free and informed consent? (Please describe the group (e.g., minors). Append a copy of the information letter and permission form you will use to seek permission from the subsitute decision maker, if applicable. Describe and justify the method you will use to seek the permission of the parent or legal guardian.

◯ Yes ◯ No

6. Describe plans for ongoing consent to ensure that consent is current and if necessary, to convey new information.

7. Do you intend to recontact participants regarding future studies? If yes, ensure that you seek their permission at the present time for this intention.

◯ Yes ◯ No

SECTION J

PARTICIPANT WITHDRAWAL

1. Where applicable, please describe how the participants will be informed of their right to withdraw their participation from the study. Outline the procedures that will be followed to allow them to exercise this right.

2. Should a participant withdraw their participation form the study, indicate:
(a) What will be done with the participant's data.
(b) Any consequences that withdrawal may have on the participant.

3. Will there be a certain point during the data collection where participants will no longer be able to withdraw their data from the study? If yes, please include those constraints in the informed consent process.

FEEDBACK AND DISSEMINATION OF RESEARCH RESULTS

1. Feedback:
Please describe the plans for offering participants feedback about the details of the study.
(Append the feedback form that summarizes the purpose of the study, researcher's contacts, resources relating to unanticipated issues, REB clearance information and contact, etc., when applicable.)

2. Disseminating the research results:
Indicate how the results will be communicated to participants and other stakeholders (advocacy groups, scientific community), i.e., group debriefing, end of study letter, publication, participants will be invited to contact researchers, thesis/dissertation, presentations, mailed, emailed, posted on website at the research site, via University link/Investigator link, other appropriate means to the individual/group.)

3. Is there a need to translate the results of the research to a different language for your participants? ◯ Yes ◯ No

SECTION K

ADDITIONAL INFORMATION

Use this section, to provide any additional information:

SECTION L

INVESTIGATOR ATTESTATION

CONTINUING RESEARCH ETHICS REVIEW REPORTING REQUIREMENTS

REPORTS OF NEW INFORMATION AND UNANTICIPATED ISSUES: Any new information or unanticipated issue or event that increases the level of risk to participants or has other ethical implications is reported to the REB without delay, (within 1 business day).

REQUESTS FOR CHANGES TO CLEARED RESEARCH (Form 2): Proposed changes to the initial proposal may involve changes to the research methods, the informed consent process, research materials as well as changes to the title of the research, changes to research personnel names, roles, institutional status or contact information and funding. Changes to the research should not be implemented without documented clearance from the REB.

ANNUAL STATUS REPORT (Form 3): Research ethics clearance is valid for 1 year at a time. At the minimum, Continuing Research Ethics review consists of an annual review. A report is submitted 30 days prior to the expiry of the clearance and extends the clearance for additional year(s).

END OF STUDY REPORT (Form 5): Since one of the primary purposes of the REB is to protect human research participants, a research is deemed to be complete when involvement with and risk exposure to participants has ended. If no further recruitment of research participants will take place and data collection is complete an end of study report should be submitted.

FUNDING STATUS: Any changes to the funding status must be reported to the REB throughout the life cycle of the resarch project.

SMU REB RESEARCH MATERIALS AND CLEARANCE DOCUMENTS: I will retain a copy of the research materials and the research ethics clearances for my records.

NON-COMPLIANCE: I understand that the REB is obligated to report any cases in which a research protocol does not hold a valide Certificate of Ethical Acceptability/Continuation to the Dean of Research under the provision of the Saint Mary's University Policy on Integrity and Research Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct.

My signature confirms understanding of the following responsibilities:

I will ensure that all procedures performed under the project will be conducted in accordance with the SMU REB's approved protocol and consenting process, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2018) and all relevant Saint Mary's University, provincial, national and international policies and regulations that govern research involving human participants. Recruitment of participants will not start until the SMU REB and relating contract/agreements have been cleared by the appropriate research institute official(s). I will oversee the conduct of this research and ensure that all persons assisting with the research are appropriately qualified and adequately informed about the protocol and their research related duties.

FACULTY SUPERVISOR

I have reviewed and approve the scientific merit of the research and this ethics protocol submission and will review and approve all forthcoming requests to the REB. I will provide the necessary training and supervision to the student investigator throughout the project. I will ensure that the level of risk inherent to the project is managed by the level of research experience that the student investigator has combined with an extent of oversight that will be provided by me.

THIS PDF FORM WILL LOCK ONCE SIGNED.

1. A copy must be saved before inserting the first signature. This would allow any later editing activity to the form should applicants need.
2. The first signature will lock the form and make any later editing unavailable.
3. Before the first signature, fill all fields on the form, including the fields below.
4. Signatures are inserted using Adobe Sign available on this document. Draw and/or insert a personally drawn signature.
5. Auto-generated signatures are not accepted by the Board. Contact sas@smu.ca to learn about how to draw/insert personal signatures. Personal marks and lock functions serve an important required standard and achieve genuine records for investigators and REBs.

_____

Signature of Faculty Supervisor | (Type name) | Date (dd/mmm/yyyy)

PRINCIPAL INVESTIGATOR

_____

Signature of Choose role | (Type name) | Date (dd/mmm/yyyy)

CO-INVESTIGATOR

_____

Signature of Choose role | (Type name) | Date (dd/mmm/yyyy)

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Signature of Choose role | (Type name) | Date (dd/mmm/yyyy)

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Signature of Choose role | (Type name) | Date (dd/mmm/yyyy)

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Signature of Choose role | (Type name) | Date (dd/mmm/yyyy)