**What to Include in “Invitations to Participate” and “Consent and Assent Forms” with Templates**

(Revised February 2023)

[Note: Many of the following points are based on Tri-Council guidelines. Most of the quotations included below are taken from a Tri-Council document entitled “Sample Consent Form and Checklist”.]

**Preamble**

Frequently, research participants will be given both an Invitation to Participate and a Consent/Assent Form. What will be appropriately included in each will differ to some extent from project to project. The practice is for the investigator(s) to provide an Invitation to Participate Form in which there is a detailed description of everything potential participants should know in order to decide whether they wish to participate. The actual Consent/Assent Form then becomes a brief document, in which the participant attests that they have had the research clearly explained, that any questions have been answered, and that voluntary consent/assent is being granted. As such, the invitation to participate is a critical component of the informed consent process. The REB scrutinizes the invitation to participate closely to ensure the information provided to participants is complete and accurate.

**Consent versus Assent**

Individuals who do not have the authority to consent to participate in research must still provide their assent. "Assent" is an active affirmation of a desire to participate and differs from "consent" which is recognized as being granted from an individual with the legal authority to do so. Even very young children or those with limited cognitive ability can assent and they can certainly indicate a desire not to participate, which must be honoured. If the individual giving assent is able to read and write then assent should be documented using an assent form, otherwise assent should be obtained through a conversation with the participant (largely taken from: [http://www.irb.uconn.edu/consent\_process.html May 18](http://www.irb.uconn.edu/consent_process.html%20May%2018), 2007).

Normally when any participants recruited from the school system (pre-college and pre‑university) are 16 years or older, signed informed consent is to be obtained from both the participant and the parent/guardian. If participants are under the age of 16, including preschool children, assent is to be obtained from the participant in addition to signed informed consent from the parent/guardian. All post school system participants are to give signed informed consent unless deemed legally incompetent by some appropriate authority to provide such consent. If the latter is the case, signed informed consent must be obtained from the person(s) assigned with the authority to make decisions on behalf of the participant and assent must be obtained from the participant.

**Broad Consent for Data to be Deposited in Repository for Access by Other Researchers**

“Broad consent applies to the storage and secondary use of participants’ data and human biological materials collected for research purposes. The use of broad consent is in the context of future research using data and human biological materials with no direct contact or intervention with the participant at that time.” (p. 61 TCPS-2 2022)

Researchers seeking broad consent must describe the data and/or materials to be deposited and the potential purpose of re-use of such data/materials. Separate options for consent must also be provided for participation in the research and for the storage of the data for future unspecified research.

**1. Invitation to Participate and Consent/Assent Forms: What Should be Included in Each?**

* an explicit invitation to participate;
* an acknowledgement that participation is voluntary;
* a statement of the purpose of the research;
* a concise but clear description of the project;
* an explanation of what will be required of those who participate so that, the potential participant is in a position to make an informed decision about whether to participate;
* a statement of the time demands involved in participation;
* a statement about the benefits of participation to participants, to the group to which they belong &/or society more generally;
* if there are any potential costs for the participants other than those of time, a statement of the potential harm(s) that could result from participation;
* a description of plans for dissemination of the results;
* a statement indicating that by providing consent participants have not waived any rights to legal recourse;
* disclosure of funding/sponsorship;
* a statement about how and where data will be stored;
* contact information, including an institutional telephone number, institutional email address, as well as institutional snail mail address for the principal investigator (and, for graduate students, of the supervisor) should there be questions or concerns;
* and, identity and contact information of the appropriate individual outside of the research team whom participants can contact regarding possible ethics issues. Normally, this person will be the chair of the Research Ethics Board.

**2.** **How Elaborate Should the Invitation to Participate and Consent/Assent Forms Be?**

In Canada, the Invitation to Participate and Consent/Assent Forms have become more elaborate since the Tri-Council guidelines were established. Such forms should nonetheless be kept *as brief as possible while including required information*. In addition to the above information which is required of all projects, other topics will depend upon the specific nature of the research, the nature of the participant population, and the level of risk the research entails. *Forms that are too long and too complex are unlikely to be read or at least read carefully, defeating the goal of informed consent*.

**3.** **What Tone Should be Used?**

The general tone for the Invitation to Participate and Consent/Assent Forms should be impersonal. Do not, for example, include a statement about your personal goals in conducting the research. Such information could be construed as placing pressure on potential participates, suggesting that participation is not entirely voluntary.

**4.** **What Writing Level Should be Used?**

The wording in the Invitation to Participate and Consent/Assent Forms should be of a sort that can be readily understood by all potential participants in your research. Depending on your participant pool, therefore, the appropriate writing level could vary enormously. When in doubt, it is probably best to “go simple;” some writers on the topic suggest that a grade four vocabulary is most appropriate for research involving the general population! In any case, keep in mind that the technical terminology you might use when talking to another investigator in the field about your research is *not* appropriate for the Invitation to Participate and Consent/Assent Forms.

In some cases, where the literacy level of some participants could be low, the Invitations to Participate and Consent/Assent Forms may need to be read aloud to them. The wording of the Invitations to Participate and Consent/Assent Forms should reflect this (e.g., “I have read or have had the Invitation to Participate explained to me, and all my questions about the research have been answered”).

In situations where reading ability is raised as an issue by applicants, the REB generally requires a Flesch Kincaid grade analysis. This can be conducted directly within Microsoft Word and is provided in a pop-up window immediately following a spelling and grammar check. Other directions for completing a Flesch-Kincaid analysis can be found at https://www.mystfx.ca/research-ethics-board/home.

**5.** **And, More Specifically:**

1. In developing your Invitation to Participate Form, it is recommended by the Tri-Council that you use headings such as the following:
* Title of Research
* Name of Researcher(s)
* Invitation to Participate
* What is the Study About?
* What Will I be Expected to Do? Including the Time Commitment
* Will Anyone Know What I Said?
* What Happens If I Change My Mind and Wish to Withdraw?
* What are the Potential Benefits and Harms Associated with Participation in the Study?
* Where and How Will My Data Be Stored?
* Where Do I Get Questions Answered?
1. If you find it necessary to use an Invitation to Participate Form that is more than one page long, page numbers should be included. Invitations to Participate should normally not exceed 2 pages in length.
2. On both the Invitations to Participate and Consent/Assent Forms you should include the title of your research. This need not be the formal title from, for example, your SSHRC or NSERC application; it is recommended by the Tri-Council that you use a simplified version of the title if the one you are using is “particularly cumbersome or vague.” Your title should be easily understood by your potential participants. The title used on both the invitation to participate and the consent form should be identical to the title used on the REB application form. If they are not identical, a justification for the discrepancy should be included in the application.
3. The identity of the principal investigator(s) should appear **immediately below the title** of the research project. This should include the name(s), department(s), and institutional affiliation(s). It should also include their role in the research project (e.g., Research Director, Graduate Student, Medical Director). The names, departments, and institutional affiliations of all co-investigators on the project should also be included here. In the case of honours theses, supervisor names, departments and affiliations should also be included. In the case of Master’s or PhD research, supervisor names, role in research (e.g., supervisor), departments and affiliations should be listed at the bottom of the invitation.
4. Provision of Contact Information:
* The Tri-Council suggests that an invitation should be offered to contact the investigator with any questions.
* **If you are a Faculty member**
	+ List yourself as the contact person. Provide all contact information, including your institutional mailing address, e-mail address, and telephone number. Please do not use personal email addresses or telephone numbers.
* **If you are a student**,
	+ you should indicate that the research is being carried out as a part of the requirements for a degree from StFX. The consent form used by undergraduate students should list their thesis supervisor as the contact person, providing all the usual information including a mailing address, e-mail address, and telephone numbers. The student’s own StFX email address should also be included. Students should not include personal or non-StFX work information like home or work addresses (either physical or email) or phone numbers. Masters and PhD students should include the supervisor’s name, department, affiliation and contact information on the consent form.

Do *not* indicate on the Invitations to Participate and Consent/Assent Forms that your project has the approval of the StFX Research Ethics Board. Approval granted by the Board is for the ethical portion of the research only and does not indicate more general support for the project.

Please include the ROMEO number assigned to your study on all recruitment documents (e.g., recruitment advertisements), as well as Invitations to Participate and Consent/Assent Forms when you submit your revised and final application.

Each participant must be given a copy of the Invitation to Participate for their own records.

Have each participant in your research sign *two* copies of the Consent/Assent form, one for your records and one which the participant will keep (this is the participant’s record of how to contact you or a Supervisor).

If you intend to distribute the results of your study to those participates, please indicate how you will do this.

See the next page for a template form for the invitation to participate.

**Template -- Invitation to Participate Form**

***\*\*Headings shown in this example should be used exactly as they appear. They should be presented in bold and in the order given here.***

**Title of Research**: [See #5c, above]

**Name of Researcher(s)**: [See #5d and #5e, above] Provide the name, position, and contact information for the principal investigator and any co-investigators.

**Invitation to Participate**

Potential participants should be explicitly invited to participate in the research. The means by which they may signal their agreement to participate should be specified (e.g., by contacting the investigator or signing an appended Consent/Assent form). Participants should be informed that by providing consent, they have not waived any rights to legal recourse.

Undergraduate and graduate students should include the fact that the research is being conducted as part of the requirements for an undergraduate or graduate degree (as relevant) in the Department/School of \_\_\_\_\_\_\_\_\_\_\_\_\_ at St. Francis Xavier University, in Antigonish, N.S.

**What is the Study About?**

A clear description of the nature of the proposed research is necessary if potential participants are to make an informed judgment about whether to agree to participate. Although the description should be comparatively brief, the nature of the research being proposed must still be clear to the reader.

“A brief description of the *purpose* of the research should explain the topic that is being explored or the hypothesis that is being tested and what the research is supposed to find out. The description should be in language that is comprehensible to individuals in the population from which the participants are being drawn. If there are specific inclusion and exclusion criteria for research participation, these can be noted here.” (Tri-Council, undated, p.2)

If the research project is funded or sponsored, a statement about the funding agency or organization sponsoring the research should be provided.

**What Will I be Expected to Do, Including the Time Commitment**

“A step-by-step description of the research as it will be experienced by the research participant must be provided, and it must clearly explain the expected length of their participation in the research. The objective is to provide the prospective research participant with a clear understanding of they will be involved in the research (e.g., completion of a questionnaire, answer questions of a personal nature in a private interview, testing of a new drug, surgical intervention, or being asked to solve problems). In addition to describing each phase of the research protocol, it is important to include an explanation of the following, where appropriate:

* whether any specific testing is required to determine eligibility for research participation (e.g., a vision or hearing test, a psychological test, HIV testing);
* whether the research design involves specific research techniques such as randomization, sequential assignment, blinding, or placebo control, and, if so, an explanation of those techniques in lay terms;
* whether any records (medical, school, work) will be reviewed;
* whether research participation will result in missed school or work;
* whether radiation is involved and, of if so, the level of radiation to which the participant will be exposed;
* whether blood testing is involved and, if so, the amount of blood that will be taken.

For some research protocols, including most of those involving patients and many involving research in schools, it is important to explain:

* which interventions are part of standard practice and which interventions are purely research;
* whether any clinical treatment, education practice, or other type of intervention that is being received will be altered or discontinued as a result of research participation;
* whether research participation will require additional visits to the hospital or lengthen hospital stay or require extra time at school;
* whether the service/drug/intervention/device/programme will or will not be available to the participant once the research is complete, assuming that it is found to be beneficial. (It is expected that, where appropriate, the researcher will attempt to secure agreement from the sponsor to continue to provide the service/drug/intervention/device programme to research participants beyond the original research time frame, until it is available in a regular context.” (Tri-Council, undated, pp.2-3)

Include a statement about any compensation that participants will receive (e.g., refreshments, honorariums) and how this will be handled in the event that participants withdraw their participation. Discuss any expenses that participants are likely to incur and whether/how these will be reimbursed.

**Will Anyone Know What I Said? *(as applicable to your project)***

* 1. Investigators sometimes confuse “anonymity” and “confidentiality”; you may need to consider this distinction before writing this section of your consent form. The distinction between the two terms made by the REB is that when anonymity is guaranteed, no one—including the investigator—will be aware of who has supplied what information. Anonymity is mostly applicable to questionnaires where the participants’ names are never given.

In the case of confidentiality, the investigators and possibly other individuals (e.g., a transcriber, a graduate student’s thesis supervisor) may know who supplied what information, but the participant is guaranteed that every effort will be made to ensure that no one else becomes aware.

* 1. The Tri-Council notes that confidentiality is not guaranteed in all research projects; any limits on confidentiality should be particularly clearly spelled out.
	2. Include whichever of the following are appropriate for your research.
* “There are limits to confidentiality for discussions held in group settings.”
* “Participation or non-participation will be kept in confidence.”
* “Pseudonyms will be used for participants.”
* “Pseudonyms will be used for schools, communities, places of work, etc.”
* “The transcriber of the tapes will be bound by the principle of confidentiality.”
* “The tapes and transcripts will be kept in a secure place.”
* “No identifying information will be included in any document resulting from this study.”

A brief statement about how the results will be disseminated should be provided.

**What Happens if I Change My Mind and Wish to Withdraw?**

“The prospective research participant must be told very explicitly that they have the right to refuse to participate in the proposed research and, moreover, that a decision to participate in the research is not binding. It is important to make clear that participant withdrawal may be made at any time without negative consequences. Prospective research participants should be told that pre-existing entitlement to care, education and other services will not be prejudiced by the decision on whether to participate or to continue participation once the research has begun. Accordingly, a physician should ensure that a patient realizes that continued clinical care is not linked to research participation. Similarly, a teacher should not recruit prospective participates from a class or from students under their supervision, without REB approval of the procedures to be followed to ensure that consent is freely given and that education alternatives are available for students who choose not to participate. For research in the school system, it is important that there be options for children who do not participate that are of equal education value and that do not single them out for teasing by classmates.” (Tri-Council, undated, pp.6-7)

“The prospective research participant should also be told that they will be given continuing opportunities to decide whether or not to continue to participate.” (Tri-Council, undated, p.7)

“It is equally important to advise participants that withdrawal of their participation does not necessarily include withdrawal of any data compiled up to that point.” (Tri-Council, undated, p.7)

Include whichever of the following are appropriate for your research.

* The way(s) in which a participant could signal their intention to withdraw from the study should be specified.
* The decision to withdraw from the study at any point shall be without negative consequences.
* The participant has the right for the recording to be stopped at any point upon request.

Participants have the right to refuse to answer any questions without having to terminate their involvement in the research project.

* If a participant should choose to withdraw from the study, indicate whether the data provided to this point will/will not be destroyed.
* Indicate clearly that a participant’s continued access to [care, education, other entitlements] will not be jeopardized if they should decide to withdraw from the study before it is completed.

**What are the Potential Benefits and Harms Associated with Participation in the Study?**

**\* (Please list *benefits* *before* *harms*)**

The direct potential benefits *to the prospective research participant* must be stated explicitly. “If there are potential benefits *to the participant*, these should be described as accurately as possible. This description should include relevant information about the nature of the potential benefit(s) (how important are these benefits?) and the probability of occurrence (how likely is it that the potential benefits will occur?).” (Tri-Council, undated, p.5)

“In research projects where there may be anticipated benefits to society or to a specific group within society (e.g., persons with a particular disorder, consumers interested in a particular product, children learning to read), these potential benefits must be explained in a separate paragraph so as not to confuse potential benefits to others with potential benefits to the research participant.” (Tri-Council, undated, p.5) It is important not to overstate the potential benefits as this could be construed as placing undue pressure to participate.

This section is not intended to describe benefits to the primary investigator or the success of the research project itself.

Compensation or inducements to participate are not considered benefits of participation.

 “If there are no known or anticipated harms associated with the proposed research, this should be stated explicitly. In any case, there should be a statement acknowledging the possibility of unforeseen harms” (Tri-Council, undated, p.4). For low risk projects, the following has been suggested by the Tri-Council as a possible wording: “There are no known harms associated with your participation in this research. However, there may be harms that we don’t yet know about.”

“The Invitation to Participate Form should describe all foreseeable harms, including physical, emotional, and psychological harms and inconveniences (e.g., adverse reaction to a drug, loss of self-confidence after poor performance on a memory test, regret over the revelation of personal information to an interviewer, disruption of family routine, long waits, boredom, revelation of personal information). If there are known potential harms or inconveniencies to the research participant, these should be described as accurately as possible in easily comprehensible language. This description should include relevant information about the nature of the potential harm(s) (how serious is the potential harm?), and the probability of occurrence (How likely is it that the potential harm will occur?) As well, information concerning the possibility of reversibility should be included along with a description of any precautions that will be taken to minimize the probability of occurrence.” (Tri-Council, undated, p.4)

“…if there is a possibility of harm from the revelation of the prospective participant’s identity, that possibility must be described in the written section on Potential Harms” (Tri-Council, undated, p.5).

***Note on Potential Benefits and Harms****: “The Tri-Council Policy states that REBs should require a more thorough discussion of reasonably foreseeable harms and benefits in the Invitations to Participate and Consent/Assent Forms for research related to treatment, research using invasive methodologies, and research where there is a potential for physical or psychological harm.” (Tri-Council, undated, p.5)*

**Permission of Other Bodies**

For research that requires the participation of one or more agencies (e.g., a school board, health unit, or government department), indicate what body or bodies has/have given permission for this research to be carried out.

**Alternatives**

“When the research includes patients as participants, it is important that the prospective research participant know whether there are any ‘treatment’ alternatives. If there are no such treatment alternatives (i.e., no available therapy), this should be stated. If there are treatment alternatives, the alternatives should be described and this description should include a summary of the nature of the alternative intervention(s), as well as the potential harms and benefits. As well, the potential participate should be informed of what care to expect if they decide not to participate in the research study.” (Tri-Council, undated, p.5)

**Where and How Will My Data Be Stored?**

Information should be provided on how the data will be stored and kept secure (e.g., password protected computer, locked filing cabinets).

 Information should be provided about if and when the collected data will be destroyed. Although individual disciplines may have standard practices that should be followed, the REB recommends that, in the absence of such discipline based standards, graduate students should keep their data for two years following completion of the research and Faculty members should retain their data for five years following publication.

If the data will be placed in a data repository the invitation to participate should include information about what data will be stored and for what purpose it might be used. Please see Article 3.13 of TCPS 2 (2022).

“There is a distinction between details of the research that are known versus details of the research that are uncertain or cannot be specified at the time of consent. An important part of the consent process, therefore, is informing participants of areas of uncertainty that may be relevant to their decision to participate. Researchers should consider what information is meaningful to the participant’s decision to participate at the time of consent.” (p. 63 TCPS 2 2022)

The invitation may include the following (as applicable):

* + A statement about what data and/or human biological materials will be stored;
	+ A statement about the voluntariness of consent including any limitations on the feasibility of withdrawal of data;
	+ A description of the nature and types of future research that may be conducted and its purpose;
	+ A statement about the benefits and risks of storage including areas of uncertainty where risk cannot be estimated;
	+ A general description of the data repository;
	+ A statement regarding participants’ preference to being recontacted for additional future research;
	+ A statement about whether data could be shared with researchers who are not subject to the TCPS-2 and/or whether the potential research might be conducted outside of Canada.

**Miscellaneous**

In this section, please provide additional information as appropriate.

In some instances, it will be appropriate to state that “the proposed intervention is for research rather than education, treatment, or other purposes.”

**Where Do I Get Questions Answered?**

Include complete institutional contact information (i.e., institutional mailing address, office telephone number, institutional e-mail address) for the investigator and, if you are a graduate student, for your research supervisor. Do not include personal email addresses, mailing addresses, or telephone numbers.

Please also provide the identity and contact information of an appropriate individual outside of the research team whom participants can contact regarding possible ethics issues. Normally, this will be the chair of the Research Ethics Board.

Include the Romeo number that has been assigned to your study.

Note that an Invitation to Participate does not require signatures. This is reserved for the consent form.

**Template -- Consent Form**

“There should be a statement to the effect that the prospective research participant:

* has read and understood the relevant information;
* understands that they may ask questions in the future;
* indicates free consent to research participation by signing the research consent form.” (Tri-Council, undated, p.7); and,
* separate options for consent to participation in the study and storage of the data in a long-term repository for future unspecified use must be provided.

I have received a copy of the Invitation to Participate for the research project titled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have had an opportunity to read the information provided or it has been explained to me\*, and have had all questions that I may have had answered.

I agree to participate in this research project, understanding that I am doing so voluntarily, that confidentiality will be maintained, and that I have the right to withdraw from the study at any point using the means outlined in the Invitation to Participate.

Signature

Date:

If you plan to deposit the data in a repository for future unspecified use by other researchers, include the following (as applicable):

I agree to permit my data to be deposited in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name or describe repository) for future unspecified research. I understand that I am doing so voluntarily. I understand that my data will be stored \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(describe level of identifiability of the data), and that I have the right to withdraw my data at any point using the means outlined in the Invitation to Participate.

Signature

Date:

**Note:**

You should provide complete contact information for the Principal Investigator.

For research involving participants who cannot give legal consent, the wording “Parent’s or Legal Guardian’s Signature” should be used.

Two copies of the consent form should be signed, one for the researcher and the other to be kept by the participant or, in the case of participants who cannot give legal consent, by their parent or legal guardian.

Where consent is provided by parent or guardian, include a space for the name of the participant (although a signature is not required).

If the research participants are children, include a statement for the parent or guardian to sign such as “I have explained the research to my child.”

\* For certain cases it may be necessary to read aloud the covering letter to some

potential participants who may have limited literacy levels.

**\*\*** The consent form should not repeat all the information in the Invitation to Participate form. Be as brief as possible.

**Template -- Assent Form**

Individuals who do not have the authority to consent to participate in research must still provide their assent. "Assent" is an active affirmation of a desire to participate and differs from "consent" which is recognized as being granted from an individual with the legal authority to do so. Even very young children or those with limited cognitive ability can assent and they can certainly indicate a desire not to participate, which must be honoured. If the individual giving assent is able to read and write then assent should be documented using an assent form, otherwise assent should be obtained though a conversation with the participant (largely taken from: [http://www.irb.uconn.edu/consent\_process.html May 18](http://www.irb.uconn.edu/consent_process.html%20May%2018), 2007).

Two copies of the Assent form should be signed by the investigator, one for the investigator and the other to be kept by the participant or by the parent or legal guardian.

The undersigned investigator hereby certifies that they have discussed the research project with [name of participant] and have explained the information contained in this document, including the reason for the research, the risks, and the benefits or potential benefits. The undersigned investigator further certifies that the participant was encouraged to ask questions and that all questions were answered.

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_