

1 April 2016

Commonly Requested Changes

All applicants must use the most recent version of the application which is available on the REB website.

Completing the Invitation to Participate and Consent Forms

General Note

The Research Ethics Board recommends that you **use headings** such as the following in your Invitation to Participate as a way of drawing the attention to key issues.

- The Name of the Study
- What is the Study About?
- What Will I be Expected to Do?
- How Much Time will it Take?
- 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 Do I Get Questions Answered?

1. Invitation to Participate

- a. The Invitation to Participate should be clearly **labeled** as such.
- b. The subject or purpose of your project should be provided - in non-technical terms - at the beginning of your letter.
- c. Provide a concise but clear description of your project. In order to make an informed decision about whether to participate, potential subjects need to have a clear idea of the nature of the research. In the words of the Tri-Council policy statement, "a brief description of the purpose of the research should explain that topic that is being explored or the hypothesis that is being tested."
- d. Your name(s) and complete contact information, e.g., mailing address(es), telephone number(s), and e-mail address(es), should be provided.
- e. If you are a graduate student, the supervisor's name and contact information must also be provided. Indicate that the project is being carried out in connection with your graduate studies in the _____ department or school at St. Francis Xavier University.
- f. You must **request participation**; it cannot be assumed. Such a request should be made explicitly in the Invitation to Participate, e.g. "You are invited to participate in ..."
- g. The wording of your letter throughout should be straight-forward and nontechnical (i.e., plain language) so the meaning will be clear to all intended readers. In the words of the Tri-Council policy statement, "the description should be in language that is comprehensible to individuals in the population from which the participants are being drawn."

- h. The Invitation to Participate should state explicitly that participation is voluntary.
- i. In order for potential participants to consent to participate, the nature of the activities in which they will be **involved** should be specified clearly.
- j. The Invitation to Participate should indicate the approximate amount of time that will be required of the research participants. If there is more than one activity (e.g., interview and focus group), give the estimated amount of time for each activity and then give the total amount of time required.
- k. For research where there are potential costs for the participants other than those of time or effort, a statement of the potential harm that could result from participation should be clearly described. For instance, a possible effect in a focus group is that “others’ opinions of you may change as a result of participating in the group.”
- l. If there is a possibility of harm from the revelation of the prospective participant’s identity, that possibility must be described. If there is an existing relationship between participant and researcher, then you need to emphasize that this relationship will not be affected by the decision to participate, not participate, or withdraw.
- m. For low-risk research, the Tri-Council policy guidelines suggest that you include a statement such as: “There are no known harms associated with your participation in this research. However, there may be harms that we don’t yet know about.”
- n. The participant needs to know how to withdraw, what the consequences are, and what happens to their data. “If I should choose to withdraw from the study at any point, such withdrawal is without consequences.” Note that a participant’s continued access to care/education/other entitlements will not be jeopardized if he or she should decide to withdraw from the study before it is completed.
- o. Please specify the means by which a participant may signal his or her wish to withdraw from the study. (e.g., by telling you directly or leaving the interview)
- p. If audio-taping is involved, let the participants know that they can stop the taping: (e.g., “I understand that I have the right for the taping to be stopped at any point I request.”)
- q. Let the participants know that they can refuse to answer particular questions: (e.g., “I understand that I may refuse to answer any questions without having to terminate my involvement in this research project.”)
- r. Have a statement about what will happen to collected data if a participant withdraws. For example: “If you should choose to withdraw from the study, the **data** you have provided to this point will be kept unless you specifically request that they not be.” You may also point out that data collected up until withdrawal will be kept, if there is reason for doing so.
- s. Information should be provided about how long the collected data will be kept before being destroyed. Although the TCPS does not specify a required time for the retention of research data, the Board’s recommendation is that the data for a project being done as part of a graduate degree should be kept for two years after the completion of the project. Faculty research data would normally be kept five years after the publication of the study (although in some disciplines the convention is to keep it indefinitely).
- t. Indicate what bodies or bodies (e.g., school boards) have given permission for this research to be carried out.

2. Issues Related to Confidentiality

- a. The Invitation to Participate should clearly indicate that confidentiality will be maintained, if that is what you intend. You might say, “No identifying information will be included in any document resulting from this study.” Indicate if you plan to use pseudonyms for the individual participants, schools, institutions, or organizations.

- b. If you plan to use their real names, which may be appropriate in rare cases, participants need to know this upfront.
- c. Researchers sometimes confuse “anonymity” and “confidentiality”; you may need to consider this distinction before re-writing this section of your Invitation to Participate. Anonymity is usually only possible in a survey/questionnaire.
- d. The details of how confidentiality will be maintained should be made clear in the Invitation to Participate letter. (e.g., “Your participation or non-participation will be kept in confidence.”)
- e. Given the potentially sensitive nature of some of the subject matter, the transcriber (if other than the researcher) should be bound by the principle of confidentiality: “I understand that the recorded interview will be transcribed and the information will be kept confidential.” You will need to include a confidentiality form for the transcriber in your application.
- f. It is important to keep the transcripts confidential and secure. The Board recommends that the consent forms and transcripts of interviews be separated and kept in separate locations. You might use wording such as: “The transcript of the interview will not be identified with your name and it will be labelled with an identification number [or pseudonym]. Your identity and number [or pseudonym] and any other identifying markers will be kept confidential by the researcher.” [Note: use either “identification number” or “pseudonym,” whichever is appropriate for your study.]
- g. You need to say where and how the data will be stored. e.g., “The recording and transcript will be kept on a password-protected computer.” You might also include safeguards such as firewalls and anti-virus software to protect data from unauthorized access, loss or modification.
- h. In the case of a group interview or focus group, it is difficult to maintain confidentiality. You might use this wording. “There are **limits to confidentiality** for discussions that are held in **group settings**.”

3. Consent Form: General

- a. The “Consent Form” should clearly be labeled as such.
- b. The Consent Form should not repeat all the information in the Invitation to Participate. You might use wording such as, “I have read the Invitation to Participate (or, have read or had the Invitation to Participate explained to me) and have had all my questions about the study answered.”
- c. The text should read “Parent’s or Legal Guardian’s Signature.”
- d. Your own name and complete contact information (i.e., mailing address, telephone number, e-mail address) should be included.
- e. The participant should sign **two copies** of the consent form, one to keep and one to give to the researcher.

4. Possible Problems with the Research

A major issue concerns a possible power relationship between the researcher and the participant. **Research carried out by a supervisor or teacher on participants whom he or she teaches or supervises** create its own ethical concerns. In most circumstances, any assessment/grading done by a teacher should be completed before the research begins. There may also be ways to have a third party recruit and collect data so that there is no conflict of interest or perceived power relationship between the researcher and the participants.