BCIT

Research Ethics Board

Guidelines for Creating an Informed Consent Document

Creating a consent document for research participants is one part of the informed consent process. The primary purpose of the consent document is to provide information to prospective research participants to enable them to give "free and informed consent about participation." Consent documents must conform to standards created for voluntariness and understandability. Some of these standards include, but are not limited to, using:

- Type size - no smaller than the type on this page (12 point)
- Headings, small paragraphs and spaces between the paragraphs
- Simple lay language (Grade 8 education; see Readability Statistics option in MS Word) - explain technical terms, acronyms and jargon as you would to someone in middle school.
- Single person and tense throughout the document (i.e., do not switch from 'you' to 'I' or refer to participant in third person).
- Page numbering format of: Page 1 of 3, Page 2 of 3, Page 3 of 3, etc.
- Only one document, the consent form, containing all information required by the participant. Do not use attachments or participant information forms.

The consent form submitted for review should be in its final form (as it will be seen by the participant), including:

- Letterhead of the primary research site (use logo) and logos, if available, from any other institutions with shared responsibility.
- Corrected spelling and grammar
- Identifiers on the consent document (i.e., version date or number of the consent form)
- When you re-submit any changes to the consent form, whether changes are requested by the sponsor or by the REB, highlight all changes clearly.

On the following pages, you will find a template to assist you in writing your own consent form. Examples of common items and headings have been included with acceptable versions of standard statements. Neither this, nor any other consent form template, should be blindly copied. The final responsibility for ensuring that the consent form is understandable and complete is yours, however please feel free to ask for advice or assistance by emailing, Chair, BCIT Research Ethics Board at research_ethics@bcit.ca.

[*name and address of research site, plus logos of any other participating institutions]*
e.g., *Department, School*
British Columbia Institute of Technology
3700 Willingdon Avenue
Burnaby, BC V5G 3H2

RESEARCH CONSENT FORM

TITLE: **[INSERT TITLE AS IT APPEARS ON THE APPLICATION]**

PRINCIPAL INVESTIGATOR: **[NAME AND PHONE/EMAIL]**
NOTE: A STUDENT GENERALLY CANNOT BE A PI (SEE EXCEPTION BELOW), SO PLEASE LIST A STUDENT AS A "RESEARCHER". THE PI IN THIS CASE IS THE STUDENT ADVISOR

CO-INVESTIGATORS: **[NAME AND PHONE/EMAIL IF APPLICABLE]**

[NAME AND PHONE/EMAIL IF APPLICABLE]

FACULTY ADVISOR: **[NAME AND PHONE/EMAIL IF APPLICABLE]**
NOTE: THIS IS USED FOR A RESEARCHER WHO QUALIFIES TO BE A PI BUT ALSO HAS AN ADVISOR (E.G. FACULTY MEMBER WHO IS A PHD STUDENT)

STUDY COORDINATOR: **[NAME AND PHONE/EMAIL]**

SPONSORS: **[NAMES OF ALL SPONSORS, GRANTING AGENCIES, AND COORDINATING GROUPS]**

24 hour telephone number: **[If applicable]**

INVITATION
You are being invited to take part in a research study because [*insert details*]. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives [*and doctor if applicable*] if you wish. Ask us questions if there is anything that is not clear or if you would like more information.

WHAT IS THE PURPOSE OF THE STUDY?
[Brief but complete description of the purpose of the project and of all procedures to be carried out in which the participants are involved. Your description should be written at a level of language and detail that someone with a Grade 8 education and no prior knowledge of your project could understand]

WHAT IS BEING TESTED? (IF APPLICABLE)
[Indicate if the project involves a new or non-traditional procedure whose efficacy has not been proven in controlled studies]

WHY ARE YOU BEING INVITED?
Because you are... [Inclusion criteria here]

You should NOT take part in this study if you… [Exclusion criteria here]

Do not exclude participants based on age or ability unless justified in the ethics application. TCPS2 discourages restriction of participation based on age or other characteristics except for safety reasons. Consent to participate in research is based on capacity rather than provincial age of majority. Participants capable of reading the consent form (Grade 8) and understanding the risks of minimal-risk research generally have the capacity to consent.

DO YOU HAVE TO TAKE PART?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign this consent form. If you do decide to take part, you are still free to withdraw at any time and without giving any reason.

CAN YOU BE ASKED TO LEAVE THE STUDY?
If you are not complying with the requirements of the study or for any other reason, the researchers may withdraw you from the study.

WHAT WILL YOU NEED TO DO IF YOU TAKE PART?
[Describe the activities or procedures, including the total amount of time that will be required of a participant]

HOW WILL MY INFORMATION BE USED?
[Describe how study results will be reported (e.g., presentation, graduate thesis, journal article, etc.) and how the participant can receive a summary of the results (e.g., participant provided a mailing/email address or provide website and availability details)]

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?
[Describe all known risks (e.g., psychological, cultural, privacy, confidentiality), and a description of the procedures in place to minimize risks or to provide counselling or referral for those in distress. State “no known risks” if none]

WHAT ARE THE BENEFITS OF TAKING PART?
[Describe the possible benefits, if any, to the participant. If there are no potential benefits to the prospective research participant, this must be stated explicitly. If there are any anticipated benefits to society or to a specific group describe these in a separate paragraph so as not to confuse potential benefits to others with potential benefits to the research participant]

WHAT HAPPENS IF SOMETHING GOES WRONG? (IF APPLICABLE)
In case of an emergency, the following person can be contacted for further information: [*name*] at [*Tel No:* ___].

In the event that you become injured while participating in this study, necessary medical treatment will be available at no additional cost to you or your medical plan. This will be covered by [*the sponsor's*] liability insurance.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
[Provide assurance that the identity of the participant will be kept confidential and description of how this will be accomplished, i.e., describe how records in the principal investigator's possession will be coded, kept in a locked filing cabinet, or encrypted under password protection if kept on a computer hard drive, and how long personal information will be kept before being destroyed. In the case of printed questionnaires, a statement discouraging participants from writing their name or other identifying information. Describe where de-identified data may be kept for future use, if applicable. BCIT policy 6600 requires primary data to be kept for verification for a minimum of five years. Promise anonymity only in cases where participants are not identifiable such as a survey where email is not collected for a prize draw and where IP tracking has been turned off in the survey settings.

If audio or video recording is being used, describe how you will ensure the confidentiality of the recordings and who will have access to them. The eventual fate of the recordings must also be disclosed (i.e., where and for how long they will be stored and whether they will be destroyed, any plans for secondary use).

If video recording is involved, specify what will be captured on the video and explain that those not participating will not be recorded. See guidelines for more information on using video conferencing in research.

If data records are kept on a computer hard disk, describe how the security of the computer record will be maintained. Note: Do not say that the information will be kept confidential, since it will be published.

NEW (2024): If survey software or Zoom/Teams or other video conference software is used, Canadian data residency is preferred. The safest alternative is EU data residency, as the EU's GPRD (General Data Protection Regulation) has very strong privacy regulations. If the software you use does not have Canadian data residency, you *must* inform the participant. This used to be a legal requirement under the previous version of Canada's privacy regulation FOIPPA, but now remains an ethical requirement. For US data residency, privacy cannot be guaranteed to the same degree due to the Patriot Act.

If the study involves focus groups, it should be noted that only limited confidentiality can be offered. For example, include a sentence that says something like, "We encourage participants not to discuss the content of the focus group to people

outside the group; however, we can't control what participants do with the information discussed."

If they study involves video conferencing, participants should be told that they can protect their identity and increase the protection of their personal information if they use only a nickname or a substitute name, turn off their camera (if the research allows for this and they would like to do this, and mute their microphone when it is not needed. If you are recording the session, please notify the participants.

In circumstances where the study is likely to facilitate the disclosure of behaviours or actions where there are legal limits to confidentiality, a more detailed statement regarding these limits should be provided. For example, you could include a statement that says something like: "At any point in the study, if you reveal that there has been an incident that involves abuse and/or neglect of a child or an elderly person (or that there is a risk of such occurring) please be advised that the researcher must, by law, report this information to the appropriate authorities".

Researchers may be required to make their data publicly available at the time of publication. This requirement may come from both funders such as the Tri-Councils and journals – which may decline to publish papers unless the data is publicly accessible. If there is the potential for your research data to be publicly available, please add to the consent form:

a. A description of what open access means, where the data will be stored, and who will have access to it.
b. A description of the data that will be publicly available, e.g., de-identified. Ensure terms and definitions are provided in lay terms.
c. Acknowledgement that making the data public has the potential for increasing participant risk (if applicable).
d. An explanation that once the data is made publicly available the participant will not be able to withdraw their data.]

WHO IS ORGANIZING AND FUNDING THIS RESEARCH?

This study is sponsored by [*insert all individuals, institutions, agencies, companies contributing funds, personnel, equipment, space, etc.*]

[Declare any actual or potential conflicts of interest regarding possible benefits from commercialization of research findings and remuneration received from the sponsor that are above or beyond reimbursement for costs to conduct the study, such as additional payment for conducting or being involved with any part of the study (e.g., study design)]

[*Insert personnel and institution*] have received financial compensation from [*name the sponsor*] for the work required in doing this clinical research and/or for providing advice on [*the design of the study/travel expenses/etc.*]. Financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers and the sponsor. Researchers must serve the interests of the participant and

also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.

WILL YOU BE PAID FOR BEING IN THIS STUDY?
[Describe any remuneration, including any partial compensation. If you make the payments specific to each visit they should not be withheld until the end of the study and should be available to those who withdraw (e.g., "You will receive $__ in consideration of your time and towards your parking or transportation costs for at each visit").

For prize draws, include wording such as "If you want to participate in the prize draw (excluding Quebec residents), please contact ____. You do not need to complete the study to enter. The odds of winning and number of prizes are ___. If you win, you will need to successfully answer a skill-testing question in order to receive it." Please see guidelines under Project Details—19.8 Compensation.]

NEW (2024): Note that it is illegal in BC to exclude from a prize draw participants who withdraw from a study, so it needs to be both a) *possible* to the withdrawing participant to participate in the draw and b) the means to do so must be *made clear* to the participant (example: asking for an email at the end of a survey when a participant that withdraws may not get there is problematic, unless it's possible to skip to that part of the survey where the email is asked, and this is clear to the participant).

There will be no costs to you for participating in this study. You will not be charged for any research procedures.

CONTACT FOR FURTHER INFORMATION.
If you have any questions or desire further information with respect to this study, or if you experience any adverse effects *(if applicable)*, you should contact [*Principal Investigator*] or one of their associates at [*telephone number*/email].

If you would like a [*summary of the study/invitation to presentation*] when available, please contact…

If you have any concerns about your treatment or rights as a research participant, you may contact the chair of the BCIT Research Ethics Board at 604-432-8554 or research_ethics@bcit.ca

Thank you for reading this.

WHY ARE YOU SIGNING THIS CONSENT FORM?
By signing this consent form, you agree that:

- You have read and understood the information in the consent form dated [*date of REB certificate*] and have had the opportunity to ask questions.

- You understand your participation is voluntary, that you may refuse to participate and that you are free to withdraw at any time before or after starting participation.
- Withdrawing will not [*jeopardize further treatment, jeopardize medical care or influence class standing, as applicable*].
- You are not giving up your legal rights nor do you release the research investigator, BCIT or the study sponsor from their legal and professional responsibilities.
- You have received a copy of the consent form for your records.
- You agree to take part in this study.

You agree to be photographed for [*describe use*] Yes___/No___; recorded by video for [*describe use*] Yes___/No___; recorded by audio for [*describe use*] Yes___/No___.

SIGNATURE(S)
[if applicable—for online consent replace with "Having read the above, you understand that by clicking the "Yes" button below and completing the questionnaire you agree to take part in the study."]

Signature of participant	Date (written by participant)
Printed Name of participant	
Signature of legal guardian/representative [*where participant is unable to consent, see application instructions*]	Date
Signature of person conducting informed consent discussion [*where participant is unable to read form*]	Date
Signature of witness [*where participant is unable to read form*]	Date
Signature of Investigator [*optional*]	Date