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 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 tool 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]**

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

[NAME AND PHONE/EMAIL IF APPLICABLE]

FACULTY ADVISOR: **[NAME AND PHONE/EMAIL IF APPLICABLE]**

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 THE [EXPERIMENTAL ITEM OR PROCEDURE] BEING TESTED?
[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 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?
[Description of the activities or procedures, including the total amount of time that will be required of a participant]

WHAT ARE THE ALTERNATIVES FOR TREATMENT?
[If treatment exists...]
You do not have to take part in this study to receive treatment for your [disease or condition] since there are other medications. The research doctor will be happy to discuss these with you.

HOW WILL MY INFORMATION BE USED?
[*Describe how study results will be reported (e.g., 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.]*

WHAT ARE THE BENEFITS OF TAKING PART?
[Describe the possible benefits, if any, to the participant. If there are any anticipated benefits to society or to a specific group describe this in a separate statement.]
Quote from Tri-Council Policy Statement:

"If there are no potential benefits to the prospective research participant, this 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?)

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.

WHAT HAPPENS IF SOMETHING GOES WRONG?

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 product] liability insurance.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

[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.

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.

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.

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."

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 publically available at the time of publication. This requirement is coming both from funders such as the Tri-Councils and journals – which may decline to publish papers unless the data is publically accessible. If you intend to make your research data publicly available, please add to the consent form:
a. A statement about the potential for future use and what that means within the context of the research.
b. A statement about the nature of the data that will be publically available, e.g., de-identified. Ensure terms and definitions are provided in lay terms.
c. An acknowledgement, if making the data public has the potential for increasing participant risk.
d. A statement indicating that once the data is made publicly available, the participant will not be able to withdraw their data.]

We will make every attempt to keep any information that identifies you strictly confidential. All documents will be identified only by code number and kept in [a locked filing cabinet.] You will not be identified by name in any reports, publications or presentations resulting from this study. Your research records may, however, be inspected by the [representative from Health Canada (HC) or] a representative of the [sponsor] but only in the presence of the Investigator or their designate. Copies of relevant data which identify you only by code number may be required by [HC, the FDA or sponsor], but you will not be identified by name unless required by law.

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).

e.g., The Principal Investigator [insert study personnel and/or institution] has received financial compensation from the sponsor [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?

[Once you are enrolled in the study, at each visit we will [pay / reimburse / give] you $XX [towards your parking and transportation costs… cover your …..] [*Note: make the payments specific to each visit relevant to the procedures at that visit. Do NOT withhold payments until the end of the study.]*

There will [will not] be costs to you for participating in this study. You will [not] be charged for [the study drug(s) or] any research procedures.

Thank you for reading this.

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, you should contact [Principal Investigator] or one of [his/her] associates at [telephone number].

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, (insert name), at (insert phone number) or research_ethics@bcit.ca

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 *[include date of REB approved ethics form]* 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.
- By signing, you agree to take part in this study.

SIGNATURE(S)

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