



Research Ethics Board

Guidelines for Creating an Informed Consent Document

Creating a consent document for research subjects is one part of the informed consent process. The primary purpose of the consent document is to provide information to prospective research subjects 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 - explain technical terms, acronyms and jargon as Ann Landers would explain it
- single person and tense throughout the document. i.e. Do not switch from 'I' to 'you'.
- 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 subject. Do not use attachments or subject information forms.

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

- letterhead
- 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.

Letterhead

[name, address and
phone of research
site]

RESEARCH CONSENT FORM

TITLE:

PRINCIPAL INVESTIGATOR: [NAME] [phone]

CO-INVESTIGATORS: [NAME AND PHONE IF APPLICABLE]

[NAME AND PHONE IF APPLICABLE]

STUDY COORDINATOR [NAME AND PHONE]

24 hour telephone number: [if applicable]

INVITATION

You are being invited to take part in a research study. 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 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?

[Use Ann Landers-type vocabulary to describe the purpose of the study. What is the question that you're trying to answer?]

WHAT IS THE [EXPERIMENTAL ITEM OR PROCEDURE] BEING TESTED?

WHY ARE YOU BEING INVITED?

Because you are/have.....

You should NOT take part in this study if you....[add the exclusion criteria]

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?

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.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

WHAT ARE THE BENEFITS OF TAKING PART?

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 a 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?

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 THE RESEARCH?

The study is sponsored by: [company, city, country and contact person]

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 subject, you may contact the Chair of the BCIT Research Ethics Board by emailing 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.
- The principal investigator or research coordinator have answered your questions to your satisfaction.
- You understand your participation is voluntary and that you may refuse to participate or you are free to withdraw at any time.
- You are not giving up your legal rights nor do you release the research investigator, BCIT nor the study sponsor from their legal and professional responsibilities.
- You agree to take part in this study.
- You will receive a copy of the signed consent form for your records.

SIGNATURES

Signature of subject or legal representative
(if participant under 19 years of age)

Date (written by subject)

Signature of witness

Date (per witness)

Signature of person conducting informed consent discussion

Date (per person conducting discussion)

Signature of Investigator

Date (per investigator)