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 that enables them to give free and informed consent to participate in research. Consent documents must conform to standards created to support understandability and voluntariness. Some of these standards include, but are not limited to, the following:

- Type no smaller than that on this page (11 point).
- Headings, small paragraphs, and spaces between the paragraphs.
- Simple lay language to explain technical terms, acronyms, and jargon.
- Consistent personal pronouns and verb tense throughout the document.
- 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 research participant. Attachments or participants' information forms should not be used.

The consent form submitted for review should be in its final form (as it will be seen by the subject) and should include these components:

- Letterhead
- Correct spelling and grammar
- Identifiers on the consent document (i.e. version date or number)
- Where applicable, clearly highlighted changes (i.e. changes requested by the sponsor and/or REB are to be indicated on resubmitted documents)

On the following pages, you will find a generic letter to assist researchers in writing consent forms. Examples of common items and headings have been included with acceptable versions of standard consent form statements.

Neither this example, nor any other consent form template, should be blindly copied: researchers are responsible for ensuring that their consent forms are understandable, complete, and appropriate for their projects.

For advice or assistance, the VCC Research Ethics Board can be reached at REBsupport@vcc.ca.

[Letterhead]

[name, address, phone number , and email address of research site]

RESEARCH CONSENT FORM

TITLE:

RESEARCH ETHICS BOARD NUMBER:

PRINCIPAL INVESTIGATOR: [NAME] [phone]

CO-INVESTIGATORS: [NAME; PHONE IF APPLICABLE]

[NAME; PHONE IF APPLICABLE]

STUDY COORDINATOR [NAME AND PHONE]

24-HOUR TELEPHONE NUMBER/EMAIL: [if applicable]

INVITATION

You are being invited to take part in a research study. Before you decide whether or not to participate, 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 straightforward 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?

You are invited to participate in this study 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?
The researchers are permitted to withdraw you from the study if you are not able or willing to comply with the requirements of the study, or for any other reason.

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 an emergency, the following person can be contacted for further information: [name and telephone number].

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 [location of data, e.g. 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?

[**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.]*

Once you are enrolled in the study, at each visit we will [pay/reimburse/give] you [reimbursement in dollar amount] towards your [parking and transportation costs/to cover…]

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.

CONTACT FOR FURTHER INFORMATION.

If you have any questions or desire further information about this study, or if you experience any adverse effects, you should contact [Principal Investigator or associate] at [telephone number].

If you have any concerns about your treatment or rights as a research subject, you may contact the Chair of the VCC Research Ethics Board, Elle Ting, at eting@vcc.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 has answered your questions to your satisfaction.
- You understand that your participation is voluntary, that you may refuse to participate, and that you are free to withdraw from the study at any time.
- You are not giving up your legal rights nor do you release the research investigator, VCC, or 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

Please print name	Date (written by research participant)
Signature of research participant or legal representative	Date (written by research participant)
Signature of witness	Date (per witness)
Signature of investigator	Date (per investigator)