St. Lawrence College

Creating an Informed Consent Form

Creating an Informed Consent Form (ICF) for research participants is one part of the informed consent process. The primary purpose of the ICF is to provide information to prospective research participants to enable them to give "free and informed consent about participation."

Elements of a ICF:

A. The Invitation to participate in research:

- Inform prospective participants that they are being invited to participate in a research project.

B. Who is conducting the research?

- State the name of the research project, the name of the researcher (when the researcher is a student, the name of the supervisor should also be included), and the name of the institution (e.g. St. Lawrence College).

C. What is the research project about?

- Provide a brief explanation as to the purpose of the research project (in lay terms).

D. What is expected of participants?

- Provide a brief explanation as to what will be expected of the participant, including the expected time commitment.

E. What are the benefits and risks?

- Provide an explanation of the potential benefits (direct – e.g. "it may benefit you to know that you are helping advance research in [field X]" and indirect – "this

research will advance our understanding of [X] where presently there is little.") and risks (if you acknowledge the potential for risks in your SLC-REB Application then you must include those risks in the ICF). However, if there are no known risks state: "There are no know risks with participation in this study."

F. The voluntary nature of participation:

- Inform the participant that their participation in your study is voluntary and that they can either choose to participate or not and even if they choose to participate they can change their mind at a later time. Usually this also means that they can have their data removed from the study, as well, upon withdrawal. However, withdrawing a participant's data is not always practicable (e.g., data might be anonymous or anonymized or aggregated, data may already be included in submitted reports or publications). The researcher is required to provide a reasonable time for withdrawal of data (e.g., 1 month after collection of data or longer if practicable). The amount of time allowed will depend on the sensitivity of the data, the risk of harm to the participant, and the reasonableness of the time allotted.

G. How will you protect participants' privacy and confidentiality?

- Explain what information you will be collecting and what steps you will take to protect their privacy and confidentiality (e.g., "Only myself and my supervisor will have access to any information you provide me. Any information stored on a computer will be password protected [if it is on a mobile device it must be encrypted]. To protect your identity, we will give participants [e.g., a code, pseudonym]. You will not be identified in any reports, publications or presentations at conferences. All data collected will be stored in a secure location and destroyed after 7 years.")

H. Who to contact for further information?

- Explain who participants can contact for more information. For example: “If you have any questions about the research project you may contact [researcher] at [email], [Supervisor] at [email]. If you have any questions or concerns about your rights as a research participant in this study you may contact the St. Lawrence College Research Ethics Board (SLC-REB) Chair at reb@sl.on.ca “

Formatting an ICF

1. The ICF must conform to standards created for voluntariness and comprehensibility. 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
    - one person and tense throughout the document (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 participant (do not use the attachments or information forms)

2. The consent form submitted for SLC-REB review should be in its final form (as it will be seen by the participant), including:
    - letterhead
    - corrected spelling and grammar
    - identifiers on the consent document (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.

Attached is a sample consent form to assist you. Examples of common items and headings have been included with acceptable version of standard statements. Neither this, nor any other consent form template, should be blindly copied. The final responsibility is the researcher's for ensuring that the consent form in comprehensible (e.g., grade 8 reading level. You can use the Flesch-Kincaid Grade Level found in Word Tools to check the reading level of your ICF.) and complete.

*******Please feel free to ask for advice or assistance by contacting the Research Services Officer, Anthony Wright, at awright@sl.on.ca or call 613-544-5400 ext.1621.

St. Lawrence College

(Letterhead)

Date: _____

Research Informed Consent Form

Research Project Title: Should be the same as on the SLC-REB Application
Researcher: [NAME] If Principal Investigator (PI) is a student researcher, provide the name of supervisor as well.

Invitation

"You are 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. Ask us questions if there is anything that is not clear or if you would like more information."

What is the study about?

[Provide a brief explanation in lay terms the purpose of the study (i.e. what is the question that you're trying to answer?). Also explain what you are expecting the participant to do and how much time you expect them to commit to your study.]

Do I have to participate?

"It is up to you to decide whether or not you wish to participate. If you do decide to participate in this study you will be asked to sign this consent form. Even if you agree to participate in this study now, you can change your mind later. If you do decide that you no longer wish to be a participant in this study, you may withdraw from the study no questions asked."

Are there any risks or benefits?

Include the risks you have identified in your SLC-REB Research Ethics Application. If there are no known risks, only then can you state: “There are no know risks associated with participating in this study.”

Include a statement regarding benefits: “There are no direct benefits to you for participating in this study, however you may benefit from knowing that this research is [advancing research knowledge in this field] or [helping advise public policy makers].” **Note:** The Tri-Council Policy Statement (TCPS2, 2014) states: 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.

Will my information be kept confidential?

“We will make every attempt to keep any information that identifies you confidential. We will only use [e.g., a code number, pseudonym, aggregate/general information] when presenting our research data. All research information will be kept in a secure location and on password protected computers. All information stored on mobile devises will be encrypted. Only the researcher [and supervisor if applicable] will have access to any information that can identify you. You will not be identifiable in any reports, publications or presentations resulting from this study.” [If there is a duty to report by a regulatory board or law, then include this information here.]

Will I be compensated for participating in this study?

Either: 1) “You will not be compensated for participating in this study but we are grateful that you are volunteering your time.” Or 2) “Once you are enrolled in the study [you will receive a one-time payment of…] or [at each visit we will [pay / reimburse / give] you [X]

towards [e.g. your parking, transportation, cover your daycare costs, loss time at work, or as a token gift of appreciation]."

Note:

- Make the payments reasonable so as to avoid it being construed as an undue influence, negatively affecting their voluntary participation. Also make payments specific to each visit relevant to the procedures at the visit. Example: "You will receive $10 at each visit." or "You will receive $5 for every survey you complete."
- **Important:** Participants are entitled to whatever compensation you offer them even if they withdraw from the study before it is completed, so it is always best to prorate your compensation.]

Who can I contact for more information?

"If you have any questions about the research projector you can contact the [researcher] at [phone number – should not be a personal number] or [email]. If you have any concerns about your rights as a research participant or the way in which the research was conducted, please contact the St. Lawrence College Research Ethics Board Chair at reb@sl.on.ca or call 613-544-5400 ext. 1621."

Why am I being asked to sign this consent form?

This is a contract between you and me to make sure that I do what I say I am going to do. You can refer to it if ever you have any questions or are wondering who to contact for more information.

By signing this consent form, you agree that:

I have answered all of your questions and you understand what you are being asked to do in this study. Please keep a copy of the signed consent form for your records.

St. Lawrence College

Name of Participant (please print): _____

Signature: _____ Date: _____

Name of Researcher: _____

Signature: _____ Date: _____