GRENFELL CAMPUS | MEMORIAL UNIVERSITY

Informed Consent

Informed consent provides participants with enough information about the study to allow them to make informed decisions about whether to participate, and whether to continue to participate. It is an on-going process that starts with the researcher's first contact with the individual and continues through study completion/participant withdrawal, and beyond. It includes any verbal exchange about the study, the written informed consent form and any other written documentation given to participants.

Consent must be documented.

- *If written consent is possible*, the consent form should be dated, signed and the participant should receive a copy of the consent form for his or her own reference.
- *If consent has been obtained orally,* the consent form must be dated and signed by the researcher(s) indicating that "I have read and explained this consent form to the participant before receiving the participant's consent, and the participant had knowledge of its contents and appeared to understand it.
- *When a consent form is not used*, then some other means must be available for participants to indicate their consent. For example, in a survey, participants should be informed that completion and return of the survey will constitute consent to participate and permission for the researcher to use the data gathered in the manner described.
- *When written consent is culturally unacceptable*, or where there are other good reasons for not recording consent in writing, the procedures used to seek free and informed consent must be approved by the ICEHR before data are collected and must be documented.

Participants make a vital contribution to research. They must be treated at all times with the highest respect and consideration. All communications, whether written or oral, should be professional, as well as socially and culturally appropriate. Specifically:

- Information letters and consent forms should be presented on the institutional or departmental letterhead of the Principal Investigator.
- Use the second person (i.e., "you") in the informed consent process.

The level of language used should be appropriate to participants' age and comprehension level. Avoid or explain technical terms and jargon. (For people in the general population, a grade 6 to 8 reading level is appropriate. In Microsoft Word the Flesch-Kincaid Grade Level Score can be determined by accessing Tools/Options/Spelling

TEMPLATE

The Informed Consent Form should be written in plain, clear language, avoiding the use of jargon and acronyms. It should be tailored to the reading level of the participants so that they can understand what is required of them and make an informed decision about their participation.

A copy of the signed Informed Consent Form should be given to the participant and another copy retained by the researcher.

This template is provided as a convenience for researchers, and outlines only the minimum information that should be included.

This template below should be presented on Grenfell Campus, Memorial University of Newfoundland's letterhead.

Replace italicized text with information about your project.

Informed Consent Form

Title: *Title of research project as indicated on Application form*

Researcher(s): *Name(s), departmental and institutional affiliation(s), contact information*

You are invited to take part in a research project entitled *"title of research project."*

This form is part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. It also describes your right to withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is the informed consent process. Take time to read this carefully and to understand the information given to you. Please contact the researcher, *researcher's name*, if you have any questions about the study or for more information not included here before you consent.

It is entirely up to you to decide whether to take part in this research. If you choose not to take part in this research or if you decide to withdraw from the research once it has started, there will be no negative consequences for you, now or in the future.

Introduction
Begin with a statement of who you are (e.g. faculty or staff) and include affiliation. Indicate funding agency involved, if applicable. [For student research, insert: As part of my Masters/Honours thesis, I am conducting research under the supervision of Dr…].

Very briefly give the background to the study and explain its significance in terms that are comprehensible and meaningful to people in the study population.

Purpose of study:
Briefly describe the objectives or purposes of the study. Usually about one paragraph.

What you will do in this study:
Provide information on the activities in which participants will be involved so that they can make an informed decision as to whether or not they wish to participate.

Length of time:
Explain clearly but briefly the time commitment required for participation (e.g. length of time required to complete the interview or survey).

Withdrawal from the study:
Indicate

- *how participants can stop and/or end their involvement*
- *what will be done with the data collected up to the point of a participant's withdrawal, and any related options*
- *an end date after which data cannot be removed*
- *any consequences that withdrawal may have on the participant.*

Possible benefits:
List any benefits [excluding incentives or honorariums] that might accrue directly or indirectly to the participant through their membership in the study population.

List any benefits to the scientific/scholarly community or society that would justify participants' involvement in this study.

Possible risks:
Explain the potential risks of being in the study – physical, emotional, social, or financial. If there is potential risk that a participant may become upset, describe the procedure for immediately addressing the situation.

Confidentiality vs. Anonymity
There is a difference between confidentiality and anonymity: Confidentiality is ensuring that identities of participants are accessible only to those authorized to

have access. Anonymity is a result of not disclosing participant's identifying characteristics (such as name or description of physical appearance).

Confidentiality and Storage of Data:

a. *Include a statement advising participants how privacy will be maintained and their identities kept confidential. If this assurance cannot be made, specify the Limits to Confidentiality.*

b. *Describe how the data will be stored, where, for how long, who has access, when the data is no longer required, and how the data will be appropriately destroyed. (Electronic data should be stored on password protected devices)*

The GC-REB advises that you state that "data will be kept for a minimum of five years, as per Memorial University policy on Integrity in Scholarly Research."

c. *If using an on-line survey company, please include a brief version of the following statement:*

   "The on-line survey company, *name of company (e.g. SurveyMonkey),* hosting this survey is located in the United States and as such is subject to U.S. laws. The US Patriot Act allows authorities access to the records of internet service providers. Therefore, anonymity and confidentiality cannot be guaranteed. If you choose to participate in this survey, you understand that your responses to the survey questions will be stored and may be accessed in the USA. The security and privacy policy for the web survey company can be found at the following link: (e.g. http://www.SurveyMonkey.com/monkey_privcy.aspx)."

   Full and informed consent requires that this information be communicated to the participants.

Anonymity:

Anonymity is a desirable protection for participants. Where small samples and specific research topics are involved (e.g. participation in focus groups), the TCPS2 recognizes that it is extremely difficult to promise full assurance of anonymity. Therefore the TCPS2 recommends that researchers assure participants that every reasonable effort will be made to assure their anonymity and that they will not be identified in any reports and publications without their explicit permission.

Recording of Data:

Where applicable, information on the use of audio recording, video recording, photographic records, etc. must be provided. The consent form should include checkboxes for participants to indicate agreement, or not, to the use of such devices.

Reporting of Results:

Provide information on how the data collected will be used (e.g. a thesis, journal articles, conference presentation, report to an agency) and how the data will be

reported (e.g. using direct quotations and/personally identifying information, if the participant provides permission, versus reporting only in an aggregated or summarized form).

Sharing of Results with Participants:
Explain what information/feedback will be provided to participants or communities after their participation in the project is complete (e.g. report, poster presentation, pamphlet, etc.), and how participants may obtain copies of this information or the results of this study.

Questions:
You are welcome to ask questions at any time during your participation in this research. If you would like more information about this study, please contact: *Researcher's name and contact information.*

The following GC-REB Approval Statement must be included on all Consent Forms:
The proposal for this research has been reviewed by the Grenfell Campus-Research Ethics Board and found to be in compliance with Memorial University's ethics policy. If you have ethical concerns about the research (such as the way you have been treated or your rights as a participant), you may contact the Chairperson of the GC-REB through the Grenfell Research Office (GCREB@grenfell.mun.ca) or by calling (709) 639-2399.

Consent:
Your signature on this form means that:

- You have read the information about the research.
- You have been able to ask questions about this study.
- You are satisfied with the answers to all your questions.
- You understand what the study is about and what you will be doing.
- You understand that you are free to withdraw from the study at any time, without having to give a reason, and that doing so will not affect you now or in the future.
- You understand that any data collected from you up to the point of your withdrawal will be destroyed.

If you sign this form, you do not give up your legal rights and do not release the researchers from their professional responsibilities.

Your signature: (*replace italicized text as these are examples*)
I have read what this study is about and understood the risks and benefits. I have had adequate time to think about this and had the opportunity to ask questions and my questions have been answered.

☐ I agree to participate in the research project understanding the risks and contributions of my participation, that my participation is voluntary, and that I may end my participation at any time.

Include other checkboxes to obtain participant's permission, for example:

☐ I agree to be audio-recorded during the interview/focus group
☐ I do not agree to be audio-recorded during the interview/focus group
☐ I agree to be video-recorded during the interview/focus group
☐ I do not agree to be video-recorded during the interview/focus group
☐ I agree to the use of quotations and that my name be identified in any publications resulting from this study.
☐ I agree to the use of quotations but do not want my name to be identified in any publications resulting from this study.
☐ I do not agree to the use of quotations.

Etc.

A copy of this Informed Consent Form has been given to me for my records.

_____ _____

Signature of participant Date

Researcher's Signature:

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

_____ _____

Signature of Principal Investigator Date