**INFORMATION LETTER / CONSENT FORM GUIDELINES**

This is a tool to assist you in writing your own information letter/consent form. This form should be as **readable** as possible and **tailored** to your study population. The information provided here is offered as a **guideline** only – not all the listed elements are required for all research. However, if you decide not to include any of the standard information (sections I, III-VII, IX-X), you should explain to the UNBC Research Ethics Board (REB) **on a separate cover page** preceding the consent form why these requirements do not apply to your particular research project.

**Note:** Please do **not** put a statement in your consent form indicating that the study has been reviewed and approved by the REB, as this statement may unduly influence prospective participants in making an informed, objective decision regarding their participation in the study.

**Formatting Information:**

* It is recommended that you use headings, small paragraphs and spaces between paragraphs;
* Use **simple language** and **avoid technical terms and jargon**;
* Write out all acronyms the first time they appear on each page, followed by the acronym in brackets;
* Number the pages, e.g., 1 of 3, 2 of 3, 3 of 3, etc.;
* All information required by the subject/participant to make an informed decision must be included in the consent form;
* The consent form must be submitted to the REB on **departmental or institutional letterhead**;
* The consent form should be written in the second person. **Use ‘you’ not ‘I’**.

Any changes to the consent form must be approved by the REB before the research begins or continues.

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**Identify this document as an “Information Letter/Consent Form”**

**(Insert Title of Study)**

(If the study involves more than one consent or assent form, in addition to the title indicate to whom it is directed - i.e. Consent Form for Parents, Consent Form for Children, etc.)

**I. STUDY TEAM**

**(Sample heading: *Who is conducting the study?)***

**Faculty Investigator:** Include the Faculty Investigator’s Name, Program/Department/School/Institutional Affiliation, office telephone number and email address.

**Co-Investigator(s):** Include the Co-Investigator’s name, Program/Department/School/Institutional Affiliation, office telephone number and UNBC email address.

**Student Researcher:** Include the Student Researcher’s name, Program/Department/School/Institutional Affiliation, cell phone number, email address, Supervisor’s name and position, office telephone number and email address.

If the research is for a graduate degree, a statement to this effect must be included. Please also clearly indicate whether the research is part of a thesis (public document) or graduating essay (semi-public document). The participants must be informed as to what use will be made of the information they provide, and who will have access to that information.

**II. SPONSOR** (if applicable)

**(Sample heading: *Who is funding this study?)***

Name all agencies contributing funds (including grants-in-aid), resources and other products to the study.

**Sample wording**

* The study is being conducted/funded by the [name of research group, e.g. NCIC/industry funding/granting agency/].

**If applicable, include the following:**

A statement of any actual or potential conflicts of interest with respect to remuneration received from the funding agency for conducting or being involved with any part of the study.

An indication of whether (and to what extent) the funding agency(ies) are imposing any restrictions on access to or disclosure of information.

**III. INVITATION AND STUDY PURPOSE**

**(Sample headings: Why are you being asked to take part in this study? Why are we doing this study?)**

Explain in simple lay terms the purpose and goals of the study. Please also explain to participants why they are being invited to participate in the research.

**Sample wording**

• You are being invited to take part in this research study because [describe the characteristics of the sample population being recruited or the inclusion criteria].

• We want to learn more about how to help people who have/are [XXX].

* This study will help us learn more about [XXX].
* We are inviting people like you who have [XXX] to help us.

• We are doing this study to learn more about [XXX].

Include a clear statement that participation in the research is voluntary, that participants can refuse to answer any questions or undergo any procedures that make them feel uncomfortable, and that they have a right to withdraw from the study at any time, without giving a reason. Please also include a statement indicating that if they withdraw from the study, any information they have provided up to that point will also be withdrawn and securely destroyed, **unless they explicitly consent to their information being retained and analyzed.** The REB recognizes that in certain cases (e.g. anonymous surveys where specific participants cannot be identified) the withdrawal of participant information is technically impossible. In such cases, researchers must include a clear statement to that effect in the information/consent form.

**Sample wording**

• Participation in this study is entirely voluntary…; You are in no way obligated to participate in this research…

• You are free to withdraw from this study at any time. You are also free not to answer any questions that make you feel uncomfortable.

**IV. STUDY PROCEDURES**

**(Sample headings: What happens if you say “Yes, I want to be in the study”? What happens to you in the study? How will the study be conducted? What will I be expected to do?)**

Explain in simple lay terms exactly what people will be expected to do if they participate in the study. Describe the estimated total amount of time required if they participate in the research.

**Sample wording**

If you say 'Yes’, here is how the study will be conducted:

• We will ask you about [XXX].

• We will give you a form with questions to answer.

• If you decide to take part in this research study, here are the tests, treatments, and procedures that are involved [at the beginning of the study… during the study… at the end of the study…].

**If applicable, include the following:**

• If the study involves a control group, describe terms such as randomization (how it will be done – e.g. flip of a coin?).

• Describe how many sessions or visits, amount of time required for each visit, amount of time required for interviews/questionnaires, etc.

• If the study takes place in a school and involves the use of class time, include a description of what students whose parents refuse participation will do during the time that the other students are involved with the study.

• If the study involves analysis of tests or activities that are a part of regular class routine, then explain that the results of those who do not participate will not be included in the research.

• If the study involves captive populations (e.g. students, employees, inmates, in-patients), explain how they opt in and out of the study.

• If the study involves participatory action research, describe how the research process will unfold and what will be expected of the subject as a participant in the research process.

• If the study involves behavioral therapy, describe what alternatives or other treatment options are available to the subject/participant outside of the research project.

• If audio or video recording is involved, include a statement to that effect and describe under “Anonymity and Confidentiality” how you will ensure the confidentiality of the recordings and who will have access to them. The eventual fate of the records 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, etc.).

• If video recording is involved, explain that those not participating will not be recorded.

**V. POTENTIAL RISKS OF THE STUDY**

**(Sample heading: Is there any way that participating in this study could harm you?)**

Describe all known or reasonably foreseeable risks (e.g., physical, psychological/emotional, social or legal), and describe the procedures that are in place to minimize risks or to provide counseling or referral services for those in distress.

**Sample wording**

• We do not think there is anything in this study that could harm you. Some of the questions we ask might upset you. Please let one of the study staff know if you have any concerns.

• Some of the questions we ask may seem sensitive or personal. You do not have to answer any question if you do not want to.

• If, at any point in the study, you feel uncomfortable or upset and wish to end your participation, please notify the researcher immediately and your wishes will be respected.

**VI. POTENTIAL BENEFITS OF THE STUDY**

**(Sample heading: Will being in this study help you in any way? What are the benefits of participating?)**

Describe the possible benefits, if any, to the participant. If there are any anticipated benefits to the scientific/scholarly community, to society or to a specific group, describe these in a separate statement.

**Sample Wording**

• You may be helped in this study by...

• We do not think taking part in this study will help you. However, in the future, others may benefit from what we learn in this study by….

**VII. ANONYMITY AND CONFIDENTIALITY**

**(Sample heading: How will your identity be protected? How will your privacy be maintained? Measures to maintain anonymity and confidentiality)**

If you are planning to disclose the identity of study participants, this should be clearly stated. If not, include an assurance that (and an explanation of how) the participant’s identity will be protected.

Describe who will have access to their raw data (e.g. supervisor, committee members, researcher assistants?) If research assistants or transcribers are to be hired, please provide the REB with a confidentiality agreement (sample available on our website).

Inform participants where and for how long their data will be stored, how the security of the data will be maintained (e.g. in a locked cabinet in a locked office, on a password-protected computer, etc.), and how the data will be securely disposed of at the end of the storage period.

**Sample Wording**

• Your anonymity will be respected. Information that discloses your identity will not be released without your consent.

• All documents will be identified only by code number and kept in a locked filing cabinet in a locked office. Subjects will not be identified by name in any reports of the completed study.

• The information gathered from this study will be kept for [XX] years. It will then be securely destroyed [e.g. by shredding paper files, deleting digital files, etc.].

**If applicable, include the following:**

• 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 cannot control what participants do with the information discussed.”

• If the research involves a small study population it may be necessary to include a statement that anonymity cannot be guaranteed. For example, include a sentence that says something like, “We will do everything possible to protect your identity, but due to the small size of the study population, anonymity cannot be guaranteed.”

• In circumstances where the study is likely to facilitate the disclosure of behaviors or actions where there are legal limits to confidentiality, a more detailed statement regarding these limits must 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 that there is a risk of such occurring) please be advised that the researcher must, by law, report this information to the appropriate authorities”.

• In certain cases, researchers may feel an ethical responsibility to report behaviors or actions where there is no legal duty to report. Some researches may also be bound by a professional code of ethics with more stringent reporting standards than those established by law. In such cases, a detailed statement regarding the ethical limits to participant confidentiality must be provided.

* For researchers considering the use of an online survey (or any other online research tool), the REB **strongly recommends** the use of a provider that stores its data only in Canada, and which ensures that all data in its possession is accessed only in Canada. Researchers may, for example, utilize the in-house UNBC Survey Tool via the Centre for Teaching and Learning Technology (CTLT).
* Researchers may use a foreign-based survey company provided that NO personal information is collected (e.g. general opinion polls where no identifiable data is captured) OR if the explicit written consent of their research participants is obtained prior to data collection (e.g. include a clear statement that the information they provide will be accessible to persons and/or institutions outside of Canada).
* When utilizing U.S. based survey instruments where personal information is collected, researchers **must** **also** include the following statement: The information you provide though this survey may now be subject to U.S. laws, including the U.S. Patriot Act which allows authorities access to the records of internet service providers.

**VIII. COMPENSATION (If applicable)**

**(Sample heading: Will you be paid for your time/ taking part in this research study?)**

Payment, financial or otherwise, should be clearly outlined on the consent form. Remuneration or compensation should not be dependent on completion of the project, but can be pro-rated for those that withdraw before completion.

**Sample Wording**

• We will not pay you for the time you take to be in this study.

• We will not pay you for the time you take to be in this study. However, we will pay the cost of your [bus or taxi fare, childcare, parking].

* We will offer you a gift card, honorarium, etc. in appreciation for completing this study

**If applicable, include the following:**

• If course credit is available to University students, explain the process for obtaining the credit.

**IX. STUDY RESULTS**

Describe how and where the study results will be disseminated.

**Sample wording**

• The results of this study will be reported in a graduate thesis and may also be published in journal articles and books.

• The main study findings will be published in academic journal articles.

**If applicable, include the following:**

• If the investigators can provide the subject/participant with the results of the study, describe how this will be accomplished; for example, include an option on the consent form to provide a mailing address for a report on the findings or website details if study results will be made available online.

**X. CONTACT FOR INFORMATION ABOUT THE STUDY**

**(Sample heading: Who can you contact if you have questions about the study?)**

Include an offer to answer any inquiries concerning the procedures, to ensure that they are fully understood by the participant.

**Sample Wording**

• If you have any questions about what we are asking of you, please contact the study leader or one of the study staff. The names and telephone numbers are listed at the top of the first page of this form.

**XI. CONTACT FOR COMPLAINTS**

**(Sample Heading: Who can you contact if you have complaints or concerns about the study?)**

**Required Wording**

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the UNBC Office of Research at 250‑960‑6735 or by e-mail at reb@unbc.ca.

**XII. PARTICIPANT CONSENT AND SIGNATURE PAGE**

**Standard Wording**

“Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your [for example, employment, class standing, access to further services from the community center, day care, etc.]”.

• Your signature below indicates that you have received a copy of this consent form for your own records.

• Your signature indicates that you consent to participate in this study.

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Participant Signature Date

(or Parent or Guardian Signature)

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Printed Name of the Participant (or Parent or

Guardian) signing above

If the study is limited to a questionnaire, it is not necessary for the participant to sign the consent form. Instead, the consent information outlined above should be provided in a covering letter, provided it includes essentially the same information as a consent form, plus a sentence that states: “If the questionnaire is completed, it will be assumed that you have given your consent to participate in this study”.

***\*Important note:***

* The signature of a Witness is *not required* for social science and behavioral research.
* The statement “By law, this data cannot be destroyed” only applies to medical data collected in a clinical trial. If you include this statement, you will be asked to remove it.

***If applicable, include the following*:**

* On parental consent forms include a statement of choice, for example: ‘I consent/I do not consent (circle one) to my child’s participation in the study’
* Parents must be provided with a copy of the parental consent form. It is acceptable to include a separate section for signatures so that they may return the signature page or section and keep the information contained in the consent form for their own records.
* The first two bullets also apply to any other cases where an authorized third party is consenting on behalf of an individual who lacks legal capacity.
* Please note that, according to the TCPS2, “Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher **shall** ascertain the wishes of that individual with respect to participation. Prospective participants’ dissent **will preclude their participation**.”