CONSENT FORM GUIDELINES AND TEMPLATE

Informed consent is an ongoing process that should be revisited throughout the life of your research study and procedures for obtaining it may need to be modified over time. This process documents the informed consent relationship that you have with research participants, and ensures that individuals are fully informed of the risks, benefits, and voluntariness of participating in your study. There are many different types of informed consent, including oral consent, consent forms, community consent, indications of consent, etc. Please consider what is in the best interests of study participants when selecting an informed consent method.

This guideline is a tool to assist you in writing your own consent form, which should be written at a reading level appropriate for your study population and **tailored** specifically to your study population. A consent form does not need to be exhaustive. It should only contain important information that helps individuals make good decisions about participating in research.

TCPS 2 (2014) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans provides a list of information generally required for informed consent. Not all the listed elements are required for all research. Please click here for more information about *TCPS2 (2014)* and informed consent.

If you are conducting a clinical study, please use the BC Clinical Research Informed Consent Form Guide and Template.

Formatting Information:

- Type size should be a minimum 12-point font. Consider using a 13 or 14-point font size if you anticipate that participants have difficulty with written communication or visual impairments.
- The use of headings, small paragraphs and spaces between the paragraphs is recommended.
- 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.
- **Include a version number and date in a footnote at the bottom of each page of the consent form.** We ask you to include this information in case you need to amend any of your study documents in the future.
- Include the study number in a footnote at the bottom of the document.
- Only information required by the participant to make an informed decision should be included in the informed consent form.

- The consent form should be written in the second person. **Use 'you' not 'I'.** However, first person or 'I' should be used on the last page in the "Consent to Participate" section, where the participant signs the form.
- Please proofread your consent form and remove all copyediting errors.

The Research Ethics Board must approve any changes to the consent form before the research begins. Changes to an approved study and its documents are done via an Amendment.

Your application will be sent back, and approval delayed, if a complete consent form or consent document is not submitted with your application.

The information generally required for informed consent includes:

a) information that the individual is being invited to participate in a research project;

b) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;

c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

d) an assurance that prospective participants:

- are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
- will be given information that is relevant to their decision to continue or withdraw from participation in a timely manner throughout the course of the research project;
- will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal (e.g. once data are anonymized, published etc.);

e) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;

f) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

g) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, in what reasonably foreseeable circumstances confidentiality may be breached, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

h) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions, or the research sponsors;

i) information about any payments, including incentives for participants, reimbursement for participation-related expenses, and compensation for injury;

j) in clinical trials, information on stopping rules and when researchers may remove participants from a trial;

k) information about the possibility of material incidental findings (and associated management plan). Material incidental findings are most likely to occur with clinical, or genetics and genomics research. The possibility of material incidental findings does not need to be addressed in all cases and should be carefully considered before being presented to participants; and

l) information about how long data will be retained. If you plan to retain data indefinitely or share it in anonymized form with other researchers, databases, journals, etc., this must be clearly stated. Granting agencies and academic journals may require researchers to provide a clear data stewardship plan to allow sharing of data once the study is complete. If you have a data stewardship plan, this should also be communicated.

Important Consent Form 'don'ts!'

- Your consent form should be concise and clear. Do not include extraneous information that masks the actual risks and benefits of participation.
- It should not be stated to the participant that a Research Ethics Board has approved the study, since this may appear to offer a guarantee of safety. In fact, approval means only that the Committee considers the risks to fall within a scale of risks which a reasonable participant may be invited to accept, and that the risk-to-benefit (or risk-to-knowledge) ratio of the study appears favourable.
- No clause or language should be used to excuse or appear to excuse investigators or other persons or institutions involved from liability for their negligence or other fault (Health Canada, 2014). [1]

[1] Please see Health Canada's Requirements for Informed Consent Documents found at http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php#cons

Consent Form Template

SFU Letterhead

Include the SFU logo or letterhead on the top of the consent form. In the header is acceptable. If this is a multi-site study, use the letterhead of the SFU co-investigator who is sending the letter or obtaining consent from the local participants; all other investigators should be identified in the body of the document by Department and Institution.

Your consent form should be concise and clear. Do not include extraneous information that masks the actual risks and benefits of participation. The information listed below may not be applicable to all studies. Please consider what is in the best interests of your study participants when developing an informed consent method.

Identify this document as "Consent Form"

[Title of Study]

The title of the study on the consent form should be the same as the title in the application form unless the study uses deception or partial disclosure. If the study uses deception or partial disclosure it is acceptable to use a different study title.

The study number must be included on all study documents including the consent form.

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

STUDY TEAM
(Sample headings: *Who is conducting the study?)*
Principal Investigator: Be sure that 'Principal' is not misspelled 'Principle'.
Include the Principal Investigator's Name, SFU Department, and contact information.
Faculty Supervisor: If you are a student, please list your faculty supervisor and their contact information.

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

Co-investigators, Research Personnel, etc.: List those study team members who will interact with research participants and/or their data. Include their role in the study.

SPONSOR (if applicable)
(Sample headings: *Who is funding this study?)*
Name all organizations contributing funds [including grants-in-aid, grants, industry, etc.], resources, and other products to the study.

Sample wording

- *The study is being funded by the [e.g. industry funding/granting agency/].*

INVITATION AND STUDY PURPOSE
(Sample headings: *Why should you take part in this study? Why are we doing this study?)*
Explain in simple lay terms the purpose of the study. It may also be appropriate to provide an explanation of why participants have been asked to participate.

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].*

VOLUNTARY PARTICIPATION
(Sample heading: Your participation is voluntary)
This section should stress the voluntary nature of the participant's involvement in the study.

Sample wording

- *Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the education, employment, or other services to which you are entitled or are presently receiving.*

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 is the study done?)*
Explain in simple lay terms exactly what will happen to people if they participate in the study. Describe the total amount of time required if they participate in the research.

Sample wording
If you say 'Yes,' here is how we will do the study:

- *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 and procedures we will do: At the beginning of the study… During the study… At the end of the study:*

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

- Describe how many sessions or visits, amount of time required for interviews/questionnaires, **amount of time** required for each visit as well as the total overall amount of time anticipated for participation, etc.
- If you are asking **sensitive questions**, include a statement that some of the questions may seem sensitive or personal and that participants do not have to answer any question if they do not want to.
- If the study takes place in a **school** and involves the use of class time, include a description of what students who refuse or whose parents refuse participation will do during the time that the other students are involved with the study.
- If the study involves analyses of tests or activities that are a part of the **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 participants during the research process.
- If the study involves **behavioural or clinical therapy**, describe what alternatives or other treatment options are available to the participant outside of the research project.
- If **audio-** or **video-recording** or **photography** is involved, include a statement to that effect and describe under 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).
- If **video-recording or photography** is involved, explain that those not participating will not be recorded.
- If the study involves an **online survey platform**, describe under Confidentiality the location of the survey company's server and include a description of any associated limits to confidentiality. If data will be sent or stored outside of Canadian borders, this may increase the risk of disclosure of information because the laws in other countries dealing with protection of personal information may not be as strict as in Canada. Please note that SFU IT Services has helped launch a version of FluidSurveys that stores data in Canada and is compliant with BC's Freedom of Information and Protection of Privacy Act (FIPPA). Please see: http://www.sfu.ca/itservices/publishing/surveys/fluidsurveys_terms_of_service.html.
- If the study involves randomization of participants or procedures, provide an explanation of this term (how randomization will be done – i.e. flip of a coin). If you are conducting a clinical study, please use the BC Clinical Research Informed Consent Form Guide and Template.

POTENTIAL RISKS OF THE STUDY

(Sample heading: *Is there any way being in this study could be bad for you?)*

Describe all relevant risks (e.g., psychological, cultural, privacy, confidentiality), and a description of the procedures in place to minimize risks or to provide counselling or referral for those in

distress. Describe any risks to communities (e.g. stigmatization, discrimination etc.) Consider consulting any groups that may be affected by the research to assess the risk of negative impacts such as stigmatization and discrimination.

Sample wording

- *We do not think there is anything in this study that could harm you or be bad for you. Some of the questions we ask might upset you. Please let one of the study staff know if you have any concerns.*
- *There are no foreseeable risks to you in participating in this study.*

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 society or to a specific group, describe this in a separate statement. Please be careful not to overstate the benefits of your research or promise direct benefits to participants if they are unlikely or unknown. Note that the REB does not consider payment to be a benefit. Payments are used to encourage participation and should not be advertised as a benefit to participating in a study.

Sample Wording

- *You may be helped in this study by...*
- *No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.*
- *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.*

PAYMENT (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 honoraria 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].*
- *You will receive course credit of…*
- *You will receive $X for your participation in this research study even if you choose to withdraw.*

If applicable, include the following:

- If course credit is available to University students, explain the process.

CONFIDENTIALITY

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

If you are planning to disclose the identity of study participants, this should be explained, along with how you will protect those who do not wish to have their identities disclosed. Otherwise, include an assurance that the participant's identity will be kept confidential.

Sample Wording

- *Your confidentiality will be respected. Information that discloses your identity will not be released without your consent.* (If there will be any limits imposed to confidentiality, please see sample wording below.)
- *I will maintain your confidentiality to the fullest extent. I will not disclose your identity even if your information is requested via subpoena.*
- *All documents will be identified only by a unique code number and kept in a locked filing cabinet. Participants will not be identified by name in any reports of the completed study.*
- Please be careful with your use of terms (coded, anonymized, anonymous). For example, the term 'anonymous' should only be used for information that never had identifiers associated with it, such as an anonymous survey. TCPS2 (2014) provides useful descriptions of these terms in Chapter 5.

If applicable, include the following:

- If the data records are kept on a **computer hard disk or USB**, describe how the security of the computer record will be maintained.
- If the study involves **focus groups or group discussions**, it should be noted that only limited confidentiality can be offered. For example, include a sentence that says something like, "*Full confidentiality cannot be maintained in a group setting. We encourage participants not to discuss the content of the focus group to people outside the group; however, we can't control what participants do with the information discussed."*
- In circumstances where researchers may impose limits to confidentiality due to legal or professional obligations a more detailed statement regarding these limits should be provided.
    - *Your confidentiality will be respected. Information that discloses your identity will not be released without your consent unless required by law. 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*
    - *Your confidentiality will be respected. Information that discloses your identity will not be released without your consent unless required by law. If the researchers are requested to reveal information by subpoena, the researchers may reveal your identity and other information you disclose to me during the course of this study to*

the authorities.

- *Your confidentiality will be respected. Information that discloses your identity will not be released without your consent unless at any point in the study, you tell the researchers that you plan to harm yourself or others, the researchers will report this information to the appropriate authorities.*

- If the participant data/records will be shared with government departments or agencies, community partners in the research, personnel from an agency that monitors the research, and/or a research sponsor (such as a pharmaceutical company), the REB or a regulatory agency should include a sentence stating, "*Research records or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of [insert names of organizations]".*
- If the participant data is to be shared in an online repository (e.g. SFU Radar) after the study is completed, include a statement that says something similar to *"In current best practices in research, electronic data is to be preserved for future use in open access initiatives. Open access initiatives allow researchers from different universities to share their data upon completion of studies, in an effort to stimulate further use and exploration of existing data sets. Data from this study will be uploaded to an online repository and these files will be stripped of any information that could identify participants (e.g., names, email addresses), to ensure confidentiality."*
- If data (including tissues) are being transferred outside of Canada, the following information must be included in the consent form. Please note that mandatory tissue sharing must be consented to in an optional consent form if this activity is not directly tied to the objectives of your study.
    1) *Describe the participant information that will be sent outside of Canada*
    2) *Describe how the data will be coded, anonymized, etc.*
    3) *List who will receive the information (i.e., individuals, organizations, regulatory agencies)*
    4) *Indicate where the information will be sent (i.e., USA, UK, Australia)*
- If data and/or samples will be sent outside of Canada, clarify if it is data and/or samples and include the following wording: "*Any study-related data [or samples], sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study-related data [and/or samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information [or samples], to organizations located outside of Canada. [Include list of organizations.]"*

WITHDRAWAL

(Sample heading: What If I decide to withdraw my consent to participate?)

Indicate that the participant may withdraw at any time without giving reasons. Participants cannot be required to submit a request for withdrawal in writing unless participant safety will be

compromised. If you have already made this statement under Voluntary Participation above, the withdrawal statement does not need to be repeated.

Please also indicate when and how participants can withdraw their data from a study. If this is not possible, such as in the case of anonymized data, this must be explained. In addition, if you are planning to keep data in perpetuity this must also be disclosed and justified in your Study Detail.

Sample wording

- *You may withdraw from this study at any time without giving reasons and with no effects on grades, employment etc.*
- *If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be destroyed.*

ORGANIZATIONAL PERMISSION

If appropriate, you should state whether or not organizational permission has been sought. You should also include any risks this may pose to participants in the 'Risks' section of the consent document (if any). For guidance on 'Organizational Permission' refer to the Study Detail Guidelines.

Sample wording

- *Permission to conduct this research study from XYZ has been obtained.*
- *Permission to conduct this research study from XYZ has not been obtained. The risk of your participation without the organization's consent is…*

STUDY RESULTS

Describe how 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***.**
- *The main study findings will be presented at academic conferences***.**

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

If investigators plan to provide participants with study results, describe how this will be accomplished; for example, include an option on the consent form to provide a mail or email address for a report on the findings, or website details if study results will be made available online.

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 your study to ensure they are fully understood by the participant.

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 about your rights as a research participant and/or your experiences while participating in this study, you may contact Dr. Jeffrey Toward, Director, Office of Research Ethics jtoward@sfu.ca or 778-782-6593

FUTURE USE OF PARTICIPANT DATA

Describe all known future uses of the personal information/research data collected in the study. Consideration of future uses of personal information refers not just to research, but also to other purposes, such as the future use of research materials for educational purposes. It should be noted that data sharing is now becoming a mandatory activity for many granting agencies and journals; if you plan to submit de-identified or anonymized participant data to a repository (e.g. SFU's Research Data Repository (Radar)), archive, or share it with other researchers, for example, this must be explained to participants.

FUTURE CONTACT

If researchers wish to contact participants later for follow-up purposes or to participate in other studies, include this request with appropriate yes/no check boxes. Researchers are encouraged to include this request if there is any chance that they may wish to ask participants to participate in future studies.

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 [examples should be relevant to the participant and could include references to employment, class standing, access to further services from the community centre, 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.*
- *You do not waive any of your legal rights by participating in this study.*

_____

Participant Signature Date (yyyy/mm/dd)

(or Parent or Guardian Signature)

_____

Printed Name of the Participant (or Parent or Guardian) signing above

In some cases, it may not be appropriate to ask a participant to sign a consent form. Instead, the consent information could be communicated to a participant verbally or in a document and their participation in the study would be an indication of their consent. This indication of consent would need to be documented by the investigator in field notes, or by receiving a completed questionnaire, for example.

Important note:

- The signature of a Witness is *not required* unless a participant was aided in some way with consenting (e.g. blind, deaf). This person should not be the Principal Investigator or designate.

***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.'
- Parental consent forms should also include a space for the name of the child participant so that appropriate parental consent and assent procedures can be documented. Assent procedures should be age appropriate and well justified in the Study Detail.
- If you are using an interpreter, a line for the interpreter name and signature needs to be inserted.