**CONSENT FORM GUIDELINES AND TEMPLATE**

This document provides information on the informed consent relationship that you have with research participants, and helps to ensure that individuals are fully informed of the risks, benefits, and voluntariness of their participation in your study.

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 tailoredspecifically to your study. Only information required by the participant to make an informed decision should be included in the informed Consent Form.

*TCPS 2 (2018) 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.

Consent can be given verbally or in written format via a signed Consent Form or online in the case of an online survey. Please consider what is in the best interests of study participants when selecting an informed consent method.

## Document Preparation 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.
* Each study document should include a document title, so Consent Form, Recruitment Script, Interview Questions, etc.
* Each study document should also include the SFU ethics application number, the SFU logo, a version number (eg: version 1.0), a full document date (day/month/year), page numbers.
* When creating file names for your documents, please don’t use Appendix A or the study number, or the PI’s name. Please use the document title, eg: Consent Form, Recruitment Script, Interview Questions.
* 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 copy editing errors.

**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;

j. 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

k. information about how long data will be retained. If you plan to retain data for future ethically approved research studies, or share it in anonymized form with other researchers, databases, journals, etc., this must be clearly stated.

l. If there is a conflict of interest, real or perceived, this must be stated at the top of the Consent Form. Please include what the conflict is and what strategies are in place in order to minimize this.

m. 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 in the Consent Form.

**Important Consent Form Considerations:**

* + Your Consent Form should be concise and clear. Do not include extraneous information that masks the actual risks and benefits of participation.
	+ Include as many sections from this template that apply to your project, be as forthcoming and descriptive as possible.
	+ 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).
	+ Check for current COVID19 consent form requirements here: <https://www.sfu.ca/research/researcher-resources/ethics-human-research/covid-19-guidelines>

 **Consent Form Template**

## SFU Letterhead

Include the SFU logo or letterhead on the top of the Consent Form.

## Label this document as “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.).

**Include the Title of the 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.

# STUDY TEAM

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

**Principal Investigator:** Be sure that 'Principal' is not misspelled as 'Principle'.

Include the Principal Investigator’s Name, SFU Department, and contact information.

For student projects, the faculty supervisor for the Student Lead must be the study PI.

**Student Lead:** include the name of the Student Lead for project as identified in the application form.

**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 heading: *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 heading: *Why are you invited to take part in this study? Why are we doing this study?*** Explain in simple lay terms the purpose of the study. Include 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 ask you to participate in an interview.
* You will be asked to complete an online survey.
* 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, surveys, amount of time required for each visit as well as the total amount of time anticipated for participation.
* 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 decline to participate 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 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. Also include the anticipated storage plans.
* Please note that the SFU REB considers it best practice to destroy recordings as soon as possible (for example, when transcription is complete) as they are considered identifiable data. If you need to retain these recordings in fully identifiable form, then this must be justified in the Application Form and explained to participants in the Consent Form.
* If the research includes both audio/visual recording and other methods (e.g., questionnaires, interviews), the Consent Form must specify to which method(s) the respondent is consenting; e.g., some participants may consent to give an interview, but not to having it recorded. If the participants will not have a choice regarding whether or not they will be audio recorded/video recorded/photographed, this must be explained in the Consent Form.
* 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. A statement to this effect must be included in the Consent Form.

# IN-PERSON RESEARCH ACTIVITIES

If you will be conducting in-person research activities, please add a statement to the Consent Form

that indicates the following: "The research team will abide by the latest provincial health guidelines in relation to the COVID19 pandemic."

Principal Investigators have the right, but not the obligation, to add fully vaccinated status as inclusion requirement for research participants. In such a case the study Consent Form would clearly state that the participants would be required to provide evidence of their vaccination status at the start of the research study.

The Consent Forms for these studies would clearly state that the SFU research study team members are fully vaccinated, so that participants are aware of the steps the research team has taken to mitigate the risk of COVID exposure during the in-person research activities.

# 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.

Please 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. Information about incentives or payments must be stated in a separate section.

### 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 must not be dependent on the participant’s completion of the study procedures, and should 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 your time but we will provide hospitality, or childcare costs, etc.
* You will receive course credit of X.
* You will receive $X for your participation in this research study even if you choose to withdraw.

# ORGANIZATIONAL PERMISSION

This section refers to any necessary permissions that may be required in order to conduct the study. Examples of this are School Boards/Districts/Principals, employers, volunteer organizations, sports teams / leagues.

If a researcher engages participation from members or an organization without the organization’s permission, the researcher must inform participants of any foreseeable risks that may be posed by their participation (if any).

### 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. There is a risk that your employer may become aware of your involvement in this project.

# CONFIDENTIALITY AND DATA SECURITY

### Sample heading: How will your identity be protected? How will your privacy be maintained? Measures to maintain confidentiality.

**CONFIDENTIALITY**

The purpose of this section is to explain to participants how you will protect their identity and keep their involvement in the study confidential. Participants may be offered the option to be identified in research outputs such as journal articles.

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.

### 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.)
* All participants will be identified only by a unique code number or by the use of a pseudonym.
* Participants will not be identified by name in any reports of the completed study.
* 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, such as:
* Your confidentiality will be respected. Information that discloses your identity will not be released without your consent. 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.
* Please be careful with your use of terms to describe the data you are collecting or the format in which you are retaining the data, eg: 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 (2018) provides useful descriptions of these terms in Chapter 5.

**DATA SECURITY**

* Explain how long the data will be retained for, where will the data be stored, who will have access and the security arrangements in place to protect the data.
* If data, including biological materials and records, will be made available (in anonymized format) on an online repository or open access framework, this information must be included in the Consent Form so that participants can consent (or not) to this future use.
* Explain if the study data will be transferred outside of SFU and for what purpose.
* If the participant data will be shared with community partners involved in the study, this must be explained to participants in the Consent Form.

**STUDY RECRUITMENT VIA SOCIAL MEDIA**

If your study involves the use of social media as a recruitment method, please include the following statement in the Consent Form: Please note that posting to comments sections, liking or sharing on social media or other forums about this study may identify you as a participant. We therefore suggest that if this study was made available to you via a social media site or other online forums, you refrain from posting comments to protect your anonymity.

# FUTURE USE OF THE RESEARCH DATA

Describe all known future uses of the research data collected in the study. Examples of this include uploading anonymized data to an online repository / open access framework, use of study data for educational / training purposes.

# 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. Provide information to explain the process they need to follow in order to withdraw from the study, eg: who to contact and how to contact them (email, phone, etc.). Please also explain if there are time constraints and/or limitations as to when participants can request that their data be removed from the study.

If the study involves an anonymous online survey, the Consent Form must clearly explain to participants that once they submit their survey responses, it will not be possible to remove their data from the study as the researcher will not able to identify their responses.

### Sample wording

* Please note that in order to withdraw from the study, you can exit the survey at any time. However, once you press submit, the researcher will not be able to withdraw your responses.
* You may withdraw from this study at any time without giving reasons and with no effects on grades, employment or any other services you may be entitled to receive.
* You may withdraw from the study at any time by contacting a study team member listed at the start of this document.
* 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.

# STUDY RESULTS

The TCPS2 states that it is just as important to return the results of research to participants as it is to disseminate results to the research community. Include in the Consent Form how results of the study will be returned to participants in a format that is accessible to your study population.

For example, include an option on the Consent Form to ask participants if they would like to receive a copy of the study results, or include website details if study results will be made available online.

### Sample wording:

* Results of the study will be available on the following website [xxxx] from [date]. Results may also be obtained from the study PI.
* The results of the study will be presented in a community meeting / townhall.
* 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**.**

Please make it clear that participants will not be identified in any research outputs unless they have expressly consented to this.

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.

# CONTACT FOR INFORMATION ABOUT THE STUDY

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

Please include the name and contact information for the lead contact for the study, so that participants know who to contact with any queries.

# 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, please contact the Director, SFU Office of Research Ethics at dore@sfu.ca 778-782-6593.

# 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 as this consent to contact cannot be retroactively requested.

# PARTICIPANT CONSENT AND SIGNATURE PAGE

### Signature sections are only needed for Consent Forms that participants will sign.

### A signature section is not required for an online Consent Form.

### For online consent, it is sufficient to state the following:

### Yes – I have read and understood this Consent Form and agree to participate in the study.

### No – I do not wish to participate in the study.

### 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 and later change your mind, you can withdraw from the study at any time without giving a reason and without any negative impact on your grades, or employment, or any services to which you are presently entitled to receive.

* 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 Name:

Participant Signature:

Date (yyyy/mm/dd):