**Study Detail Guideline**

A Study Detail document MUST be submitted for all ethics applications regardless of the type of study. Study Details must contain a VERSION DATE in the footer. We ask you to submit all documents individually and with a version date in case you seek to amend parts of your study in the future or your study is audited. The extent of information required for each section will vary depending on the type and risk level of the study. In order to assess risk, the REB needs to understand the research process from the perspective of the participant.

*A Study Detail template is provided at the end of this document.*

Table of Contents

- Study Detail Guideline .................................................................................................................. 1
- Grant proposals ............................................................................................................................... 3
- Funding Title ..................................................................................................................................... 3
- Project title ....................................................................................................................................... 3
- Principal Investigator, Collaborators, Other Team Members .......................................................... 3
- Background ....................................................................................................................................... 4
- Study purpose .................................................................................................................................... 4
- Hypotheses and research questions .................................................................................................. 4
- Location where research will be conducted ..................................................................................... 4
- Research procedures ....................................................................................................................... 4
- Data analysis plan ............................................................................................................................. 5
- Prospective participant information ............................................................................................... 5
  - Inclusion criteria ............................................................................................................................... 5
  - Exclusion criteria ............................................................................................................................... 6
  - Number of participants .................................................................................................................... 6
  - Research with First Nations, Inuit, and Métis peoples .................................................................... 6
- Recruitment ....................................................................................................................................... 7
  - Include a detailed description of the method of recruitment: ......................................................... 7
  - Third party recruitment (‘snowball sampling’) .............................................................................. 7
- Organizational permissions and approvals ...................................................................................... 8
- Potential benefits ............................................................................................................................... 8
- Potential risks .................................................................................................................................... 9
- Psychological harms ....................................................................................................................... 9
OFFICE OF RESEARCH ETHICS

Risks to researchers................................................................................................................. 9
Designation of the study as minimal or above minimal risk.................................................. 9
Incentives................................................................................................................................ 10
Secondary analysis ................................................................................................................ 10
Deception/Partial disclosure .................................................................................................. 11
Photography, video / audio recording..................................................................................... 12
Instrumentation ....................................................................................................................... 12
Online surveys........................................................................................................................ 13
Material Incidental Findings .................................................................................................... 13
Obtaining consent ................................................................................................................... 14
Competency and capacity ....................................................................................................... 14
  Consent for minors................................................................................................................. 14
  Consent for individuals who lack the capacity to consent for themselves ....................... 16
Maintenance of confidentiality ................................................................................................. 16
  Access to the Data – Investigators and Staff ................................................................... 18
Retention and destruction of data ........................................................................................ 18
Future use of data .................................................................................................................... 19
Dissemination of results ........................................................................................................ 19
Data Management Plan .......................................................................................................... 19
Research ethics guidance documents ..................................................................................... 20
Study Detail Template ............................................................................................................. 21
Grant proposals
Grant proposals that have been peer-reviewed and funded by granting agencies (CIHR, SSHRC, NSERC, NIH, etc.) should be submitted as additional information. Please do not submit your grant proposal as your Study Details. The Study Details should be specifically written for ethics review; the grant proposal can be submitted to provide more context for the research study submitted for review.

When submitting an application for ethics review for a project that is funded and the funds are being administered by the SFU Office of Research Services (ORS), please ensure that the Principal Investigator listed on the funding award, sub-award, contract, or sub-contract, is the same as the Principal Investigator on the ethics application. The Principal Investigator must be a SFU Faculty or Adjunct Faculty member for all types of funding except MITACS. If the study is funded by MITACS, ORS will accept the SFU student or Faculty supervisor listed as Principal Investigator on the ethics Application.

Funding Source and Title
In addition, the overall study title for the ethics application may be different from your funding title; however, you must ensure that the funding title is included in question three of your ethics application. If you include this information correctly, your funding source and funding title as well as the Principal Investigator will appear on your SFU Ethics Approval Letter issued by ORE and ORS will be able to release your funds.

Project title
The title given in the application form must correspond to the title on the Study Details form and consent form, if applicable.

Principal Investigator, Collaborators, Other Team Members
Specify who your collaborators are and whether collaborators are at a different university or agency. Specify each collaborator’s role in the study (e.g., involved in data collection, data analysis, protocol development etc.) and describe their qualifications to conduct this work. It may be useful to include this information in specific section (e.g., ‘Researcher Qualifications’).

If your research team members include individuals who will interact with human research participants, their data and their biological samples, then they should also be listed on the application submitted to the ORE Database.

Specify whether the project has been given ethics approval by another agency or university. If approval has been given, please submit the letters of approval. Ensure these approvals are reflected in your application. For information about SFU and efforts to harmonize the research ethics review process, refer to our website. If you plan to conduct a
study that will be reviewed at multiple institutions, please contact ORE as soon as possible so we can help you with the ethics harmonization process.

If the Principal Investigator (PI) is a Faculty member of another university and at Simon Fraser University as an Adjunct or Visiting Faculty, there must be a regular SFU Faculty member who is a collaborator or a supervisor.

**Background**
Provide a background description or literature review that includes an explanation of the need/justification for the study. In particular, this section should explain what is unique about the study and what new research questions can be answered in order to support the ethical tenet that the proposed research has value.

**Study purpose**
Describe the main reason(s) that the study is being conducted.

**Hypotheses and research questions**
State the research questions and hypotheses (if appropriate).

**Location where research will be conducted**
Please describe all locations where research participants will be recruited and/or where data collection will occur. If the research will be conducted in another country, describe the methods for obtaining ethics approval/permits in that country, if applicable. If ethics approval or a research permit is not required for this country, please state this as well.

Please state if any students will be conducting work in regions covered by a Government of Canada Travel Advisory. In addition, include a safety plan for all involved researchers if the research is going to be conducted in areas or situations that may be considered unsafe.

**Research procedures**
Describe in a step-by-step manner the research procedures. In some cases, it might also be appropriate to describe how they differ from normal, non-research activities (e.g., a unit of instruction may be part of the regular curriculum, but the collection and analysis of the students’ test scores is part of a research project). Describe the recruitment and consent procedures as well.

Describe the period during which the study procedures will be carried out, how long each procedure will last, and the frequency of the procedures. Include how much time the participant should expect to dedicate to the study in total. Ensure that you also include this information in the consent form and that the amount of time stated is consistent in the
application, recruitment letters or posters, and consent form. Approximations are acceptable but consistency is required.

The description should include the sampling method (e.g., random sampling), group assignment (e.g., randomization), and type of research design (e.g., ethnography). If randomization is to be used, provide a clear explanation as to why this method of assignment is necessary for the research and provide a justification for each arm of the study. The study detail and the consent form should include a description of the method of assignment to one group or another in a study comparing two or more different experimental conditions.

If blinding is used, this must also be carefully justified and explained in lay terms in the consent form.

For clinical trials, please include a description of how the research study meets all of the requirements of TCPS 2 (2014) Chapter 11. If a researcher feels that a particular section of TCPS 2 (2014) Chapter 11 does not apply to their study then this must be addressed in either the Study Details or a cover letter.

Please note that according to TCPS2 (2014) Article 11.3, all clinical trials must now be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE). This is required in order to promote scientific integrity and foster transparency and accountability with research participants and society.

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

Data analysis plan
Data analysis plans should be included for all studies. The level of detail provided should be appropriate for the field of study and/or type of research. The analysis plan should include, when appropriate, detailed information regarding study outcomes (primary, secondary), sample size calculations (provide the method used and the rationale for determination of size, specify the sample size and power calculation), variables to be analyzed, time points, and how these are to be reported (means, standard deviations, proportions).

Prospective participant information

Inclusion criteria
The selection of participants must take TCPS2 2014 Article 4.1 into consideration, which states that: “Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants”. However, the TCPS2 (2014) cautions against
recruiting participants into research studies solely because they are easy to access or manipulate and highlights researchers’ special obligations toward individuals or groups whose circumstances may lead to or increase their vulnerability in the context of a specific research project or study.

The SFU REB cautions against analyses that may contribute to stereotyping of groups on the basis of ethnocultural background, sexual orientation, etc. Therefore, when the study sample includes specific groups or a range of groups and asks participants to categorize themselves according to race, ethnicity, skin colour, gender, sex, etc., the researcher must describe the nature of the analysis to be undertaken in order to assure the REB that these data will not be analyzed in such a way that unfair stereotypes may be drawn and that reports will not allow others to use the data to create unfair stereotypes. For example, in some cases and for certain types of studies, researchers may seek to employ open ended demographic filters for contentious categories such as race or gender to foster inclusivity and avoid stereotyping or marginalizing participants.

**Exclusion criteria**
If exclusions are proposed that are not germane to the research question, a justification for excluding participants on the basis of attributes such as sex, gender, culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, age, pregnancy, HIV status, etc. should be provided.

Researchers should consider the Sex and Gender Equity in Research Guidelines (SAGER)¹ when choosing their participant populations.

**Number of participants**
Sample sizes should be justified. However, it is acceptable to provide an estimate or a range for the number of participants if the exact number is not known in advance.

**Research with First Nations, Inuit, and Métis peoples**
If you are conducting your research with Aboriginal peoples in Canada, including First Nations, Inuit, and Métis peoples, it is important to familiarize yourself with *TCPS2 2014* Chapter 9 and other guidance documents such as the OAAPH² report *OCAP: Ownership, Control, Access and Possession*. In some cases it may be appropriate to seek community or band approval (or a formal research agreement) before individuals are recruited or consented into your study. However, community engagement can take many forms and should be determined in collaboration with the community of interest. Researchers must recognize that the interests of Aboriginal communities are diverse and varied. Determining the best approach to research design, recruitment, data collection and storage, etc. typically

---

¹ [https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6

² Organization for the Advancement of Aboriginal Peoples Health now known as now known as the National Aboriginal Health Organization (NAHO)
requires extensive deliberations over time with community members and relevant First Nations, Inuit, and Métis Governing Authorities.

Conversely, community engagement may not be necessary or even appropriate in some contexts. As stated in TCPS2 2014 Article 9.7 regarding critical inquiry “Research involving Aboriginal peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit or Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.” In addition, there are occasions when individual consent is sufficient. As stated in Article 9.2 “[Aboriginal people] are free to consent and to participate in research projects that they consider to be of personal or social benefit. If the project is unlikely to affect the welfare of the individuals’ communities, local community engagement is not required under this Policy.”

Those who conduct research in this area should understand that there is no standardized approach to conducting research with Aboriginal people. Work conducted in this domain is often unique and varies according to the interests of the community. When conducting reviews of this research, the REB looks for evidence that study procedures and design are grounded in the core ethics principles enshrined in TCPS2 2014: Respect for Persons, Concern for Welfare, and Justice.

**Recruitment**

**Include a detailed description of the method of recruitment:**

a) Describe how you will gain access to names, addresses, telephone numbers, or email addresses of potential participants. State whether the contact information obtained is publicly available. If not, send confirmation from the owner/administrator of the list/contact information indicating that they will send out the recruitment request on your behalf. Researchers should not have direct access to email lists/contact information that is not publicly available.

b) Attach copies of any recruitment materials such as letters, advertisements, flyers, radio or television scripts, or Internet messages. Potential participants should not be asked to write their name and/or contact information on an advertisement posted in a public place.

c) Indicate where participants will be recruited (e.g., hospital, clinic, school, prison etc.) and ensure that appropriate approvals and permissions have been obtained.

d) Some types of research such as ethnographic fieldwork or research involving Aboriginal peoples in Canada, including First Nations, Inuit, and Métis peoples, may require unique methods of initial contact. Please describe how you plan to initiate relationships with the people involved in your study.

**Third party recruitment (‘snowball sampling’)**

Snowball sampling involves contacts or participants known to the researcher facilitating the recruitment of other potential participants. Contacts should not give researchers the
names and contact information or any other detail about potential participants without first obtaining permission from those potential participants.

The ideal process would involve providing the contact with information about the study to show or send to potential participants. This ensures that the information given out is accurate and consistent. Alternatively, the PI may ask the participant to contact potential participants to determine whether that third party has any objection to the release of their name for contact.

If participants are to be contacted as the result of a confidential list (e.g., list supplied by a post-secondary institution faculty or department), describe the approval process for access to the lists. Researchers should not have direct access to email lists that are not publicly available. A letter of permission from the administrator of the list indicating that they will send out the recruitment request on your behalf must be submitted with you application.

**Organizational permissions and approvals**

If you are conducting research at a location outside the University, it is the PI’s responsibility to obtain the necessary approvals before beginning the research (e.g., obtaining permission from a school district/principal, company or public institution director, head etc., ethics approval from a Health Authority or University etc.). The PI must forward any permission or approval letters from these institutions to the ORE once received. All approval letters must be submitted to the ORE by the first anniversary of the SFU REB approval letter or your study may be terminated. The letter from organizations that do not conduct ethics review needs to indicate that the organization is aware of any potential risks regarding the conduct of the research and that there will be no negative repercussions to employees who agree or don’t agree to participate.

If a researcher engages participation from members of an organization without the organization’s permission, the researcher must inform participants of any foreseeable risk that may be posed by their participation (if any). However, in some cases involving critical inquiry, for example, seeking organizational approval may not be appropriate or in the best interests of participants (see TCPS2 2014 Article 3.6 on Critical Inquiry). Whether or not approval from these organizations has been obtained and any associated risks this may pose to participants must be included in the Consent Form and explained in your Study Detail.

**Potential benefits**

Specify the potential benefits to the participants. If there are no direct benefits, state this explicitly. If direct benefit is unknown, explain that the participant may or may not benefit from participation in the study. If benefits at a community or broader societal level are expected, these should be mentioned. You can also state that you hope the information learned from this study can be used in the future to benefit others (if appropriate) or contribute to our understanding of the topic in question.
Potential risks
Study participants must be informed of the potential physical and/or psychological risks or inconveniences associated with each procedure, test, interview, or other aspect of the study. Please also address the broader impacts of your study on individual participants and the groups to which they belong. Such impacts may include social stigmatization, threats to reputation, the creation of unfair stereotypes, and/or psychological harms such as anxiety, regret, or guilt feelings. Consider the potential for your research data to be subpoenaed and describe what you will do if that situation arises. Describe strategies to be used to minimize or manage the study impacts for participants and other affected individuals. If there are no foreseeable risks to participation, please indicate this (e.g. no foreseeable risks or no known risks) rather than stating “N/A or Nil”.

Psychological harms
Researchers should avoid assuming a secondary role as caregiver or counselor to the research participant. If there is a risk that the participant may experience increased emotional stress as a result of the interview, questionnaire, or other research procedure beyond what might be encountered in the course of one’s daily life, the researcher should have a prepared list of appropriate, available, and resources and counseling services to be handed to every individual prior to participation. Participants who may require support and counseling may not necessarily indicate this directly to the researcher and they should have this information (on hand) so that they can self-refer.

Risks to researchers
If your study involves activities that may be risky for you as a researcher or members of your research team, please include a plan for managing these risks in your Study Detail. If the study is conducted by a student outside of Canada in a region or country under a Government of Canada Travel Advisory, please state this in your Study Detail. ORE is required to notify other SFU offices of such travel. Please note that this does not necessarily mean that you cannot conduct research in these regions.

Designation of the study as minimal or above minimal risk
Researchers should perform an initial assessment of the risk their project may pose to participants and propose it for either minimal risk review or full board review with a detailed explanation as to why the research has been designated as such. TCPS2 (2014) defines minimal risk as "Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research."

Peer review is not normally required for minimal risk research but is required for above minimal risk studies reviewed by the full REB.
Incentives
Providing incentives to participants is acceptable according to TCPS2 (2014). However, voluntary consent must be free of undue influence in the form of inappropriate inducements. The SFU REB will weigh the amount of remuneration offered against the amount of time and inconvenience to the participant on a case-by-case basis.

It is considered unacceptable to have payment depend on completion of the project. If lump sum payments or draws are used, participants must receive this incentive even if they choose to withdraw from the study. Receiving an incentive cannot be contingent on study completion in order to avoid the possibility of coercion. However, it is acceptable to pro-rate the amount of compensation given to participants who withdraw before completion or to divide the research into stages, with specified remuneration attached to each stage. The selected incentive/remuneration process must be described in both the Study Details and the Informed Consent documents.

Secondary analysis
According to TCPS2 (2014), secondary analysis “refers to the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Information initially collected for program evaluation may be useful for subsequent research. Other examples include health care records, school records, biological specimens, vital statistics registries or unemployment records, all of which are originally created or collected for therapeutic, educational or administrative purposes, but which may be sought later for use in research.”

In some cases, consent may be waived for secondary analyses of identifiable information as discussed in TCPS2 (2014) Article 5.5A below. Researchers who seek a waiver of the requirement to obtain consent must address each of the criteria listed in 5.5A in their Study Details and provide the REB with a letter from the appropriate data steward that gives the researcher permission to use the data and highlights any conditions associated with this use. Ensure that the letter of permission states in what format (identifiable, anonymized, coded etc.) the data will be provided and for what purpose. The letter must also state if the data given to you complies with the intent specified in the original consent. In your study detail, please also explain what you plan to do with the data, how you will protect the data while it is in your care, and how the data will be destroyed.

Article 5.5A Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that:
   a. identifiable information is essential to the research;
   b. the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c. the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e. it is impossible or impracticable (see Glossary) to seek consent from individuals to whom the information relates; and
f. the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5A (a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

In the case of secondary analysis of non-identifiable data, TCPS2 (2014) states in Article 5.5B that “researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.” In your study detail, please explain how the data have been made non-identifiable, what you plan to do with the data, how you will protect the data while it is in your care, and how the data will be destroyed. A letter from the appropriate data steward is also required.

Deception/Partial disclosure

There are times where the consent process must be altered in order to answer research questions. In such cases, deception or the partial disclosure of study aims to participants may be ethically justified. Only research that meets the requirements of TCPS2 (2014) Article 3.7A will be exempted from full disclosure at the time of consent (see below).

Article 3.7A

The REB may approve research that involves an alteration to the requirements for consent set out in Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply:

a. the research involves no more than minimal risk to the participants;
b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c. it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and

e. the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.
In cases where the consent process is altered, researchers should make efforts to debrief participants on the true nature of the research and the rationale behind the exclusion of information. Since initially they did not give fully informed consent, they must now be given this opportunity. Participants should also have the opportunity to withdraw their data during the debriefing process if they no longer wish to remain in the study (see Article 3.7b below). Debriefing is an important mechanism to maintain the participant’s trust in the research community.

Article 3.7B
1. Debriefing must be a part of all research involving an alteration to consent requirements (see Article 3.7A) whenever it is possible, practicable and appropriate.
2. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate (see Article 3.1).

Photography, video / audio recording
If there are any plans to use photography, video, or audio recording in the research, those who will have access to the recordings and the methods used to protect the participant’s identity must be described in the Study Detail and the consent form. The eventual fate of the records must also be disclosed in the Study Detail and to participants in the consent form (i.e., where and for how long they will be stored and if the videos/audio recordings/photos will be destroyed; and if there are any plans for secondary uses of the recordings etc.). It is considered 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 Study Detail 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 Study Detail with an explanation as to why the participants cannot have a choice. These details must also be clearly explained to the participant in the consent form.

Instrumentation
Research safety is paramount at SFU and includes the development, implementation, and co-ordination of programs in biosafety, chemical safety, diving safety, field research, and radiation safety. The Environmental Health and Research Safety Department (EHRS) strives to assist the University community by addressing all safety aspects of research from practical applications, to regulatory compliance, to planning protocols.
If you are using electronic or medical instrumentation you must describe the instrumentation in your study detail. Include the CSA or equivalent approval, Health Canada approval, or approval by SFU Environmental Health and Safety Office with your ethics application. In the case of clinical trials of drugs or devices, Health Canada approval is required under Canadian federal policy. This is NOT optional. For more information about these topics, please visit the Policies and Guidelines page on our website.

**Online surveys**

If you plan to use an online survey platform in your research please make sure to explain how data will be stored safely (and where it will be stored) and how you will protect the confidentiality of participant data in your study detail and in the consent form. If data is to be stored outside of Canada, this must be disclosed to participants. Participants should also be made aware that storing data outside of Canada 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.

**Material Incidental Findings**

As explained in TCPS2 (2014), "Incidental findings is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Incidental findings are considered to be Material Incidental Findings (MIF) if they have been interpreted as having significant welfare implications for the participant."

Article 3.4 of TCPS2 (2014) asserts that researchers have an obligation to disclose MIF to participants. It is possible for MIF to emerge at various stages in the research cycle and in many different types of research including social science and behavioral studies. For example, in certain types of interview studies it may be possible for a participant to disclose abuse or neglect, which may trigger mandatory legal reporting obligations. That said, MIF are typically characterized as clinically relevant findings and are most likely to emerge from medical and genetic research. As such, UBC has developed Interim Guidance on Incidental Findings in Genetic and Genomic Research that some researchers who work in these domains may find helpful.

The disclosure of MIF involves many complex ethics issues and should be carefully considered. It would be irresponsible to disclose MIF to participants that are not scientifically valid or communicated without appropriate supports and resources. In addition, MIF may comprise life altering information that some participants may not want to receive. Participants should therefore be allowed to opt-out of receiving MIF and change
their minds over time. If you anticipate that MIF are likely to occur in your study, you must develop and submit a MIF plan within your Study Detail. If you need help developing this plan, please contact ORE for assistance. This plan should include how you will prepare potential participants for the possibility of MIF, how you will determine if these findings are in fact material, and how you will communicate these findings to participants, among other things.

If sufficiently justified, researchers may request exemptions to the obligation to disclose MIFs to participants. Some of these justifications are presented in TCPS2 (2014) Article 3.4. For example, it may be impossible to disclose MIF to a very large population of participants or the process may cause undue hardship that would jeopardize the overall success of the research endeavor.

**Obtaining consent**

Informed consent is an ongoing process that should be revisited throughout the lifecycle of your research study and 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. Participants must be able to withdraw from research at any time without penalty (i.e., not receiving incentives) and should also have the option to withdraw donated data or tissue.

There are many different types of informed consent including oral consent, consent forms, community consent, indications of consent, etc. The method of obtaining informed consent should be clearly explained and justified in your study detail. When oral consent is used, please explain in your study detail how consent will be documented (e.g., audio recorded, in a journal entry, etc.). As already explained, consent may be waived or altered if ethically justified in some cases. Please consider what is in the best interests of study participants when selecting an informed consent method.

For more information on consent forms please review the SFU ORE Consent Form Guidance and Template.

**Competency and capacity**

**Consent for minors**

As discussed below, the TCPS2 (2014) does not use age to determine best processes and practices in the consent process. Instead, researchers should justify consent methods based on the decision-making capacity of the participant.

*Rather than an age-based approach to consent, TCPS 2 advocates an approach based on decision-making capacity as long as it does not conflict with any laws governing research participation. Some children begin participation in a project on the basis of*
consent from an authorized third party (due to the determination that they lacked capacity to decide on their own behalf) and on the basis of their own assent (see Article 3.10). In these cases, if the children mature sufficiently to decide on their own behalf (subject to legal requirements), the researcher must seek the children’s autonomous consent in order for their participation to continue. Similarly, in the case of children who are unable to assent to research participation (e.g., infants) at the beginning of a project, the researcher must seek their assent to continue their participation once they are able to understand the purpose of the research as well as its risks and benefits (Article 3.3).

To help determine which approach to consent or assent is most appropriate you must consider what is in the best interests of your participants. A general rule of thumb can be found in the Rule of Sevens. According to this rule, it is generally accepted that children under the age of seven are too young to assent to research unless they prove otherwise. One should assume that youth between the ages of seven and fourteen are able to assent to research, unless there is evidence to the contrary and youth over the age of fourteen are generally assumed to be able to consent for themselves unless there is evidence to the contrary. The Mature Minor Doctrine in Canada generally assumes that individuals 16 or older can consent for themselves. In all cases (unless circumstances are very specific and involve direct benefit to participants) dissent to research *must* be observed. Indications of dissent will vary by group and should be well articulated in the Study Detail if applicable to your research (Article 3.10).

Article 3.10 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.

In some cases it may be in the best interests of children or youth to first obtain parental consent before their assent to research is sought. This may even be required when working with some organizations or institutions such as school boards. It is important that if parental consent or any proxy consent processes are to be employed in your study that measures are taken to avoid coercion of those assenting to research. As the research participant, they must not feel compelled to participate due to their proxy decision maker’s preferences.

Finally, it is important to note that all of these notions are general guidelines. The REB expects the researcher to demonstrate in-depth knowledge of their participants in their ethics application including their ability to consent or assent to research.
Consent for individuals who lack the capacity to consent for themselves

Some participants may lack the capacity to consent in research for a variety of reasons including age, health issues, cognitive capacity, etc. It is also possible that participants may lose the capacity to consent during the life of the study or their capacity may fluctuate or change over time. Nevertheless, their inclusion in research may be justified and valuable. In cases like these, researchers are expected to justify the inclusion of such persons in their studies and also clearly outline what mechanisms and methods they will employ to protect these participants (for example, through a trusted substitute decision maker, specialized assent processes, tests to determine cognitive capacity, etc.).

The issue of autonomy and capacity to consent is discussed in TCPS2 (2014) Article 1.1- Respect for Persons (see below).

“Some people may be incapable of exercising autonomy because of youth, cognitive impairment, other mental health issues or illness. While autonomy may be considered a necessary condition for participation in research, involving those who lack capacity to make their own decisions to participate can be valuable, just and even necessary. For those prospective participants, additional measures are needed to protect their interests and to ensure that their wishes (to the extent that these are known) are respected. These measures will generally include seeking consent from an authorized third party who is entrusted to make decisions on behalf of the prospective participant, based on knowledge of that person and that person’s wishes or, if such wishes are unknown, on consideration of that person’s welfare. Even when the requirements of free, informed and ongoing consent cannot be met, Respect for Persons requires involving individuals in circumstances of vulnerability in decision making where possible. This may include asking about their feelings regarding participation and/or for their assent.”

Maintenance of confidentiality

In general, researchers have an ethical duty to protect the privacy and confidentiality of participants, which includes safeguarding data (including tissue and biological fluids), protecting these data from unauthorized access, use, disclosure, modification, loss, or theft. However, in some cases, participants may wish to waive confidentiality and have their identities revealed in research data. If researchers are unsure about what is in the best interests of participants, they should discuss notions of confidentiality with them.

In your study detail you must demonstrate how the confidentiality of the data and/or tissue and participant privacy will be maintained, including hard copies of participant data (e.g., interview transcripts, completed questionnaires, field notes, etc.), audio and video recordings, electronic files, and tissue/biological fluids. Standard measures include: password protecting or encrypting electronic files and storing hard copies of study materials in a locked filing cabinet.
The TCPS2 identifies 5 different categories of data collected from research participants, each with different implications for the privacy of participants (see below). Please specify the category that will be used in the data collection process in your Study Detail.

- **Directly identifying information** – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- **Indirectly identifying information** – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- **Coded information** – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).
- **Anonymized information** – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous information** – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

As stated in TCPS2 (2014): “The easiest way to protect participants is through the collection and use of anonymous or anonymized data, although this is not always possible or desirable. For example, after information is anonymized, it is not possible to link new information to individuals within a dataset, or to return results to participants. A “next best” alternative is to use de-identified data: the data are provided to the researcher in de-identified form and the existing key code is accessible only to a custodian or trusted third party who is independent of the researcher. The last alternative is for researchers to collect data in identifiable form and take measures to de-identify the data as soon as possible. Although these measures are effective ways to protect participants from identification, the use of indirectly identifying, coded, anonymized or anonymous information for research may still present risks of re-identification.”

**NOTE:** Please do not use the term “anonymous” to describe data unless the information never had personal identifiers associated with it. This is a common error that we see regularly in research ethics applications submitted to ORE. We often need to send provisos back to researchers asking them to use the term “confidentiality” instead of “anonymity” in their study documents.

Please also consider the following when drafting your study detail:

- Telephone and email are not a secure means of communication; therefore confidentiality cannot be guaranteed. A statement reflecting this information must be included in the consent form.
- Some research may involve an increased possibility of reports of child abuse or other mandatory reportable offences. For example:
The Child, Family and Community Service Act of BC requires that anyone who has reason to believe that a child may be abused, neglected, or is for any other reason in need of protection, must report it to the Director or a designated social worker (Ministry of Children and Family Development).

- The SFU REB may require that participants be informed regarding mandatory reporting of abuse, neglect, or allegations of abuse/neglect and reporting responsibilities to the proper authorities. Legislation or judicial rulings may require other information collected in the course of research to be made available to appropriate authorities. Researchers should be fully aware of any legislation or judicial rules pertaining to their work and be equipped to protect their participants and participant data accordingly.

Access to the Data – Investigators and Staff
Give the names (if known) of those who will have access to the raw data, which may include information that would identify the participants. The research participants must also be told in the consent form who will have access to their data and what use will be made of it, either now or in the future.

Retention and destruction of data
You must discuss how long you plan to keep data (5 years, indefinitely, etc.) and disclose this length of time to participants during the informed consent process. State where and in what format the data will be retained (e.g., SFU Vault, encrypted memory stick, paper files, etc. stored in locked cabinet in SFU office). State how the confidentiality of the participants will be maintained over the period of time the data will be kept. State if and/or when the data will be destroyed and the method of destruction.

Please note that in current best practices in research, electronic data is to be preserved for future use in open access initiatives. Data is normally uploaded to an online repository*3 and these files are stripped of any information that could identify participants (e.g., names, email addresses), to ensure confidentiality.

Audio and Video Recordings are considered identifiable information. Audio and video recordings should be destroyed soon after transcription. However, in some circumstances the SFU REB may grant extended storage of the audio or video recordings if the PI justifies the extended storage and provides clear details on how confidentiality will be maintained. All of this information must be contained in the consent form. Please see consent form requirements for more detail.

---

3 SFU Faculty, staff and students may wish to store data sets in SFU RADAR (https://researchdata.sfu.ca/).
In the case of electronic storage of data, please indicate if a secure server will be used and where this server is located.

NOTE: SFU’s minimum retention requirement is 2 years. Regulatory bodies (e.g. Health Canada⁴, FDA⁵ etc.), funding agencies⁷, and journals have their own requirements for data retention and dissemination. It is the responsibility of the PI to ensure that the data will be stored in accordance with those requirements, if applicable, and to state this information in the Study Detail and consent forms, if applicable.

**Future use of data**

Describe any known future use of the data beyond the conclusion of this research project, and indicate whether participant consent will be obtained in the current consent procedure or the participant will be contacted later to obtain consent for future use. Participants must explicitly agree to any follow-up contact. Future contact without consent and REB approval is not acceptable.

If you plan to submit de-identified or anonymized participant data to a repository (e.g. SFU’s Radar), archive or share it with other researchers, for example, this must be explained in the consent form and participants must agree to this future use.

**Dissemination of results**

Whenever possible, an offer should be made to provide research participants with feedback on the findings/results of the research. Please provide specific details on how such feedback will be provided or an explanation of why it is not appropriate to your research. In the context of community-based research, mechanisms to disseminate results to the community should be demonstrated. Dissemination plans should also include academic outputs such as publications, presentations, etc.

**Data Management Plan**

Please refer to the SFU Library page for information about research data management services and the Research Data Repository.

---

⁵ https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.62  
Research ethics guidance documents

- Tri-Agency Framework: Responsible Conduct Of Research
- CIHR Ethics Office Education Workbook: Knowledge-to-Action/Ethics Framework and Scenarios
- SFU ORE Ethics forms and templates
Study Detail Template
This template outlines the various sections that should comprise your study detail. It also lists some of the topics that should be covered in each section.

Note: some topics will not be applicable for certain study types.

1. Introduction
   - Project title
   - Principal Investigator, Collaborators, and other team members
   - Funding source
   - Conflict of Interests
   - Location where research will be conducted
   - Relationship with other previously approved studies
   - Documentation of peer review or independent scientific review
   - Indication of harmonized or multi-jurisdictional research (including list of involved sites/institutions)

2. Summary of Proposed Research
   - Study purpose
   - Hypotheses and research questions
   - Research procedures and methods
   - Instrumentation
   - Data analysis plan
   - Material Incidental Findings plan

3. Prospective participant information
   - Description of the study population
   - Inclusion criteria
   - Exclusion criteria
   - Number of participants
   - Time dedicated to participation
   - Required organizational permissions and approvals

4. Recruitment methods
   - Justify methods employed
   - Incentives

5. Obtaining consent/assent
   - How will you obtain consent/assent
   - Who will obtain consent/assent
   - Competency and capacity
   - How will consent be documented
   - Participant withdrawal
6. Potential benefits (direct benefit to participants, benefit to others, etc.)

7. Potential risks (physical or psychological risks to participants, risk of stigmatizing others, etc.). Designation of the study as minimal or above minimal risk

8. Risks to researchers

9. Participant confidentiality measures
   - Data type and method of ensuring confidentiality and privacy

10. Data stewardship plan
    - Special responsibilities of data steward for this study (evaluating requests for data, authorizing access for future use of data, etc.)
    - Access to the data – Investigators and staff
    - Retention and destruction of data

11. Future use of data

12. Dissemination of results

13. References