B.C. Ministry of Health
Consent Form Criteria

"Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues until the study is complete or the participant withdraws." *(http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php)*

In general the Ministry's expectation is that project design and execution will follow the guidelines and recommendations set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) (*http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf*) -

We encourage all researchers and other data users to familiarize themselves with this document and refer to it as needed when planning and conducting projects.

With regard to the **Informed Consent Process** – please use the following guidelines when designing a consent form for the collection, use, linkage, and/or disclosure of personal information for research and evaluation purposes. This document provides high-level direction for consent form development. Researchers & project designers are strongly encouraged to refer to **Chapters 3 and 5 of the TCPS** for more detailed guidance.

The consent form must be written in plain language avoiding the use of legalistic phrases and technical terminology.
Grade 6-8 comprehension / reading level is considered to be accessible to most potential participants (i.e. excluding young children and other individuals with language or reading comprehension difficulties) (*http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php*). Consent provisions for children and other participants with special requirements are provided in the TCPS under Decision Making Capacity (Chapter 3 Part C)

While technical/clinical /medical language is sometimes required to fully describe a project, in this instance it is important to ensure that any participant (regardless of their capacity) has access to someone who can explain technical terminology and the consent process in general prior to provision of consent. Ideally this person should review the consent form with participants prior to signature.

The Ministry of Health will expect to

- review your consent letter PRIOR to use;

and

- VALIDATE all copies of signed consent letters if and where applicable.

Data will only be released for those individuals with a validated, signed consent form.

COMPONENTS OF THE CONSENT FORM

1) The project's overall objectives, the title of the project and/or program evaluation must be stated. Detail the PURPOSE for the collection, USE, LINKAGE, and/or DISCLOSURE of information. The description of the purpose provided in the consent documents must be consistent with the purpose as described in the protocol.

There should also be information about any potential for this data to be used in future projects. If future projects are anticipated, it is necessary to seek the participants' specific consent to allow their data to be used. If they do not agree –their data may not be used for future projects.

2) A list of the TYPE/ SOURCE of information that will be collected for the analysis must be provided on the consent form. This should be as specific as possible. For example if Ministry of Health data (e.g. Personal Health Number, Medical Services billing information; hospital utilizations; etc) will be accessed, this must be documented. It is insufficient to make broad statements referring to "medical records" etc.

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3) The reasonably foreseeable RISKS and BENEFITS of participation in the project should be explained clearly. When there will be no direct benefit to the participant, the participant should be made aware of this.

4) A description of the PARTIES INVOLVED (researchers, institutions, funders etc.) in the collection, use, linkage, and/or disclosure of information (including intention to share data between project teams, organizations etc.) must be provided in the consent form

5) A statement as to the PHYSICAL STORAGE and SECURITY of the data must be provided to participants

6) Statement to the INTEGRITY of the data holdings.
Example 1: All information being held in strict accordance with the Freedom of Information and Protection of Privacy Act.

7) The researcher must identify the TIME FRAME involved in the collection, use, linkage, and/or disclosure of information.
Example 1: Information will be collected for one year prior and four years following the [event/service]'…

8) There must be provision to WITHDRAW consent at <u>any time</u> without having to provide reasons for doing so. This includes provisions to withdraw consent to USE OF PERSONAL DATA and how this data will be removed or otherwise treated.

If the researcher chooses not to allow removal of data from the study datasets then a clearly stated rationale MUST be provided for not permitting the participants a choice of removing his/her data from this research and any future research. There must also be a statement that the subject may withdraw from the study, at any time, **without penalty or loss of benefits to which they are otherwise entitled such as ongoing medical treatment.**

10) There must be a declaration of ANONIMITY in all reports and publications related to the collection, use, linkage, and/or disclosure of information and results. At the same time however – it is important that participants be aware of circumstances under which researchers are legally bound to reveal personal information. This should be articulated in the consent form.

11) Project / researcher CONTACT INFORMATION must be provided for those individuals with questions or concerns about the project.

12) Provide a space for the individual to PRINT their name:

Example 1: "In granting my consent, I _____ (please print) understand the following…"
Example 2" "I, _____ (please print), hereby grant my consent to the following…"

13) It is recommended that the signature section of the consent form contain a summary of what the participant is agreeing to in volunteering to participate in the study, as well as a statement that all their questions have been satisfactorily addressed . The signature page should also include a statement that the participant has been provided with a copy of the consent form.

14) A space for applicable SIGNATURES and DATES must be provided.