

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 of Health's (Ministry) expectation is that project design, execution, and conclusion will as a minimum 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) -

The Ministry requests that all researchers to familiarize themselves with this document and refer to it as needed when planning and conducting projects.

With respect to the **Informed Consent Process** – please use the following guidelines when designing a consent form for the collection, use, linkage, and/or disclosure, retention and destruction of participant personal information for research and evaluation purposes. **Study subjects must at all times be fully informed about how their personal information will be collected, used and/or linked, retained and destroyed during the research process.**

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 (http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf)

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 (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 readily available access to someone who can explain technical terminology and the consent process in general prior to provision of consent. This person should review the consent form with potential participants (and particularly so with minors, other individuals with decreased capacity and their guardians) prior to signature.

NOTE: Draft consent forms for all projects planning to include Ministry of Health administrative data must be submitted to the Ministry of Health for review and approval PRIOR to implementation for subject recruitment.

Participant personal information will only be released for those individuals with signed consent forms. The Ministry has the discretion to request validation of signed consent letters.

COMPONENTS OF THE CONSENT FORM

- 1) Information letters and consent forms must be presented on institutional / departmental letterhead.
- 2) The title of the project and/or program evaluation, the project's overall objectives, and the study procedures must be stated. Detail the PURPOSE for the COLLECTION, and the USE, LINKAGE, of the participant's personal information. The description of the purpose provided in the consent documents must be consistent with the purpose as described in the protocol.

There should be a clear explanation of how the collection, use and / or linkage of participant personal information is the only means to answer the research question(s) definitively. The Ministry does not permit disclosure of the participant's personal information in an identifiable form beyond the research project.

There should also be information about any potential for future use of the participant's personal information in other projects. If future projects are anticipated, it is necessary to seek the participants' specific consent for each new use or linkage of the participant's personal information in the future projects. If participants have not provided informed consent for these new uses or linkages—their personal information data cannot be used for any future projects.

- 3) Any organization collecting information must ensure that an individual from whom it collects personal information is also told the legal authority for collecting it.

For public bodies engaged in research activities, personal information is collected, used, and disclosed under the primary authority of the BC Freedom of Information and Protection of Privacy Act ("FIPPA") (collection: s.26(c); use and disclosure s.35). For other organizations not listed in FOIPPA or for individual researchers, personal information is collected and used under the primary authority of the Personal Information Protection Act ("PIPA") and should be further disclosed only under s.21 of PIPA, for research or statistical purposes.

- 4) A list of the TYPE / SOURCE of participant personal information (data elements) that will be collected for the analysis must be provided on the consent form. This should be as specific as possible. For example if participant personal information retained as Ministry data (e.g. Personal Health Number, Medical Services Plan billing information; hospital utilization; etc.) will be collected, used or linked this must be documented. The types of participant personal information included in each source (e.g diagnoses, provider types, dates of service and procedures) should be described in plain language in the consent form. It is insufficient to make broad statements referring to "medical records" etc.
- 5) 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.
- 6) Where relevant, provide information regarding the possibility of commercialization of research findings and the presence of any apparent, actual, or potential conflict of interest on the part of the researcher, the researcher's institution, or sponsors. The Ministry will not provide participant personal information for market research or commercial purposes. Section

21 of PIPA also does not authorize further disclosure of personal information for market research purposes.

- 7) A description of the PARTIES INVOLVED (researchers, institutions, funders etc.) in the collection, use, linkage, and/or disclosure, retention or destruction of participant personal information (including intention to share data between project teams, organizations etc.) must be provided in the consent form. The Principal Investigator's name and other important contact names must be provided. If the name of the Principal Investigator changes over the course of the project participants must be informed of this since it is the Principle Investigator who is ultimately accountable for ensuring responsible and ethical use of the participants' personal information.
- 8) A statement as to the PHYSICAL STORAGE and ADMINISTRATIVE AND TECHNICAL SECURITY of participant personal information must be provided to participants. The Ministry of Health works closely with Population Data BC (PopData) to facilitate data access for academic researchers.

The expectation is that all academic researchers should use PopData's Secure Research Environment (SRE) to store, access and analyse approved Ministry datasets. There must be compelling extenuating circumstances to waive its use. **The decision will be made at the Ministry's discretion on a "case-by-case" basis.**

The researcher must inform participants if their personal information will be accessed, disclosed or stored outside of Canada. Participants must explicitly consent to this - it is a legal requirement under the BC Freedom of Information and Protection of Privacy Act.

- 9) Statement as to the INTEGRITY of the data holdings.

Example : All information being held in strict accordance with the legal requirements of the Freedom of Information and Protection of Privacy Act and other relevant legislations as required for specific Ministry datasets (e.g. Pharmaceutical Services Act for PharmaNet data, the Medicare Protection Act for MSP data, the Vital Statistics Act etc.)

- 10) The researcher must identify the TIME FRAME / DATA RANGE(S) involved in the collection, use, and/or linkage of the participant's personal information.

Example : Participant personal information will be collected for one year prior and four years following the [event/service]...

Provide a time frame after study completion as to when the research data/samples will be retained and when data/ sample destruction will occur. The consent form should have an expiry date based on the project termination date; any re-consent for re-use or new uses or linkages of the personal information will have a new expiry date.

As stated previously, if future research projects re-using the same participant personal information or a new collection use or linkage of participant personal information are anticipated, the researcher must make every effort to provide the relevant details to the participants (who what when why, etc.) and seek their consent to allow their personal information to be collected, used, linked or retained future research projects. If participants are not willing to allow extended retention of their personal information, the personal

information must not be retained beyond what has been consented to for the current project.

There must be provision for participants to WITHDRAW consent at any time without having to provide reasons for doing so and **without penalty or loss of benefits to which they are otherwise entitled such as ongoing medical treatment.** This includes provisions to withdraw consent for all current and future USE and / or LINKAGE of participant personal information and how this data will be removed or otherwise treated as needed in consultation with the Ministry. Administrative data linked to survey or other researcher-collected data should be deleted if the subject withdraws and requests that their administrative information be removed from the project.

If the researcher elects not to permit removal of survey collected data from the study datasets, then this MUST be clearly explained in the consent form along with the rationale for not permitting the participants the choice of removing his/her data from this research and/or any future projects. Nevertheless, if information has been collected under PIPA, s.9 concerning withdrawal of consent must be followed.

- 10) There must be a statement that articulates the participant's right to access, correct or amend their personal information.
- 11) There must be a declaration of ANONYMITY 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 (such as for reducing the risk that an individual will be a victim of domestic violence, if domestic violence is reasonably likely to occur). This obligation should be articulated in the consent form.
- 12) Project / researcher CONTACT INFORMATION must be provided in case individuals have questions or concerns about the project. The consent form must also provide contact details for an informed and neutral party to whom the participant may bring any concerns about the conduct of the project. (e.g. the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or toll free 1-877-822-8598.).

If this information changes during the course of the research project, participants must be provided with the new contact information.

- 13) Provide a space for the individual to PRINT their legal 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..."

If an individual commonly uses an alias or nickname for identification or contact purposes, that also should be documented in addition to the legal name.

- 14) It is recommended that the signature section of the consent form contain a statement that participants feel 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.
- 15) A space for applicable SIGNATURES and DATES must be provided.

ENDNOTE:

“Consent Shall Be An Ongoing Process”

TCPS2 2014 (http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf)

Article 3.3:

“Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.... The researcher has an ongoing ethical and legal obligation to bring to participants’ attention any changes to the research project that may affect them.” (This might include but is not limited to, modifications to the original project design that affect what or how personal information is used, change in Principle Investigator or contact information, etc.).