How to use this document

This document is intended to assist investigators who have projects that involve data linkages in producing consent forms that meet the requirements of the data stewards and the following UBC-affiliated and BC regional health authority REBs/RRC:

* BC Cancer REB
* Children’s & Women’s REB
* Providence Health Care REB
* Vancouver Coastal Health
* UBC Clinical REB (CREB)
* Simon Fraser University
* University of Northern BC
* University of Victoria
* Fraser Health REB (including studies involving SFU-affiliated investigators)
* Interior Health REB
* Northern Health Research Review Committee (not currently a constituted REB)
* Vancouver Island Health Authority Clinical REB

This document is intended as guidance only and should not be considered a complete guide to or an examination of all relevant issues for consideration in connection with research projects requiring consent.

The comment boxes provide information on REB and Ministry of Health (MOH) guidelines specific to each section. Please read the guidelines then delete the comment boxes when finalizing the document.

Adherence to these guidelines may not be sufficient, however, and investigators should also refer to the guidance notes and policies of the individual REBs (see [Appendix I](#Appendix_I)). Prior to project start, a copy of the consent form should be submitted to the Data Stewards via Population Data BC (PopData) for approval in order to ensure compliance with privacy legislation. Once data steward approval has been received, the consent form, along with the ethics application, must be submitted to the REB for their review and approval. Please also inquire with your REB whether this project may fall under harmonized ethics review.

 All Information required by the potential participant to make a free and informed decision to participate in the research must be included in the consent form. If any of the required sections have not been included, a consent document may be returned to the applicant for amendment.

The appendices provide more detail on specific aspects of the consent form creation.

Appendix I includes links to REB guidance notes, policies, and forms.

Appendix II includes general style and formatting guidelines.

Before you begin

1. To ensure you are using the most current version of this template, download a new copy each time you create consent forms. To use the template, you may copy this and use it as a guideline.
2. REB required wording is highlighted in yellow.
3. Data steward required wording is highlighted in green.
4. Recommended wording is in regular font.
5. Instructions are provided in *italics*.
6. Once you have completed your draft:
	1. Delete all italic content
	2. Remove colour highlighting from the remaining text
	3. Finalize the footers and remove the headers.
	4. Remove template appendices
7. Consent forms must be saved on the appropriate letterhead, as follows:
	1. BC CANCER REB requires BC CANCER letterhead.
	2. C&W REB requires UBC and/or Hospital/Program Department letterhead.
	3. PHC REBrequires UBC and Providence Health Care/Providence Clinic Letterhead.
	4. UBC CREB requires UBC Department letterhead or VCH or VCHRI letterhead, if appropriate.
	5. FH REB requires Fraser Health Authority letterhead.
	6. IH REB requires Interior Health Authority letterhead if the study will be carried out by an IH site investigator. If the study is multi-jurisdictional, addition of the IH logo to another site’s letterhead is acceptable.
	7. NH prefers not to have its logo on the letterhead; the consent form should be on the principal investigator’s institutional letterhead.
	8. VIHA REB requires VIHA letterhead.

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|  | UBC Department Letterhead and Hospital LetterheadIf the Principal Investigator is an employee of an affiliated teaching hospital the hospital letterhead is appropriate. If this is a multi-site study, use the letterhead of the UBC co-investigator who is sending the letter or obtaining consent from the local subjects; all other investigators should be identified in the body of the document by Department and Institution. |

 **[Title of Study]**

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

**Who is conducting the study?**

You are being invited to participate in a research study conducted by a *[insert university affiliation here; e.g., University of British Columbia (UBC)]* research team. You are being invited to take part in this research study because *[insert description of the characteristics of the sample population being recruited or the inclusion criteria].* We received your contact information from *[insert database/method used (e.g. consent to be part of future research given at previous study, direct recruitment in clinic)].*

Please take some time to read more about this study.

**Principal Investigator:** *[insert PI name, university and department affiliation, and contact telephone number]*

**Co-Investigator(s):** *[insert co-investigator name, UBC/Hospital Department, Institution, and contact telephone number. Note for students: UBC students should identify themselves as such and include the degree and Department. 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).]*

**Who is funding this study?**

The study is being funded by *[insert name of all agencies contributing funds, grants-in-aid, resources and other products to the study. Note for conflicts of interest: A statement of any actual or potential conflicts of interest with respect to remuneration received from the funding agency for conducting or being involved with any part of the study].*

**Why are we doing this study?**

We are doing this *[insert total length of study. eg. 12 month, 6 month etc]* study to learn more about *[insert the purpose of your study here in simple lay terms, reading level grade 7]*. We expect that the study results will help us to understand how to help *[insert the expected larger outcomes; e.g., improve the quality of life for those who have.]*. We are inviting people like you who have *[re-iterate the characteristics of the sample population being recruited or the inclusion criteria]* to help us.

**What happens if you say “Yes, I want to be in the study”?**

If you say 'Yes’, here is how we will do the study *[insert additional numbered points below if there are additional commitments associated with the study; e.g., biosample collection, re-contact for future studies]:*

**Phase 1: We will ask you to participate in *[insert number of activities]* *[insert activity here. Eg. Survey, focus group, interview].*** The *[insert activity]* will take place at *[insert location] at [insert at what point/s in the study this will take place].* The *[insert activity]* will ask you *[insert as appropriate: to respond to questions about/for your opinions on]* *[insert type of information to be collected; e.g., your general health and well-being, your attitudes towards healthcare, your lifestyle]*. We expect that the *[insert activity]* will take *[insert time; e.g. under one hour]* of your time.

**Phase 2: With your consent, we will ask to link your survey responses to some of your records from the agencies described below:** This process is called “data linkage” (please see the next section for more information about data linkage). If you allow us and if the below agencies give us approval, we will link your survey responses to the following data sources to help us answer our research questions: ***[Choose only relevant items below (a-i)]***

* 1. **BC Ministry of Health (MOH)**: We will request information from the MoH related to your health care services. For example, information about services provided to you by health professionals (for example, the doctor), hospital visits, and health insurance costs. This will be sourced from health administrative records maintained by the MoH (e.g., *[insert only relevant files; Consolidation Files, Medical Services Plan, Discharge Abstracts Database, Mental Health, Home and Community Care, , National Ambulatory Care Reporting System (NACRS)]*). Data requested will be from *[insert start date]* to [*insert end date*].
	2. **Data Stewardship Committee (DSC)**: We will request information from the DSC related to the medications that are prescribed and dispensed to you. The information in this health administrative system (PharmaNet, including Pharmacare) is collected from pharmacies in BC by the BC Ministry of Health. Data requested will be from *[insert start date]* to [*insert end date*].
	3. **BC Vital Statistics Agency (VSA):** We will request information from the VSA pertaining to registered *[insert only relevant files; births, stillbirths, deaths, and marriages]*. Data requested will be from *[insert start date]* to [*insert end date*].
	4. **Citizenship and Immigration Canada (CIC):** We will request information from CIC related to citizenship and immigration. Data requested will be from *[insert start date]* to [*insert end date*].
	5. **BC Cancer:** We will request information related to cancer diagnoses from the BC CANCER Registry file. Data requested will be from *[insert start date]* to [*insert end date*].
	6. **BC Generations Project (BCGP):** If you have participated in the BC Generations Project, we will request the information gathered through the BCGP (e.g., your survey responses about your medical history and lifestyle). This information will be requested from the BC Cancer. Data requested will be from *[insert start date]* to [*insert end date*].
	7. **WorkSafeBC:** If relevant, we will request information from WorkSafeBC related to work-related injuries and compensation. Data requested will be from *[insert start date]* to [*insert end date*].
	8. **Human Early Learning Partnership (HELP):** If relevant, we will request information about you *[insert: and your child, if appropriate]* about a range of early childhood development indicators *(e.g., physical health and emotional maturity)* from data collected in BC schools as part of the Early Development Instrument. Data requested will be from *[insert start date]* to [*insert end date*].
	9. **Population Data BC:** We will request information from the Statistics Canada Income Band file, which contains information about average incomes associated with Postal Codes. Data requested will be from *[insert start date]* to [*insert end date*].

**How will “data linkage” happen?**

In order to link the responses that you provide in your survey to the information about you that we request from the agencies described above, we will follow strict guidelines designed to maximize the privacy and security of the information about you used in the study. The data linkage process will be completed by Population Data BC (PopData). PopData is a multi-university organization dedicated to data access, protection and privacy of research data. PopData acts as a trusted third party for data linkage. Data linkage for this study will include the following procedures:

* We will ask you for your Personal Health Number *[insert here: any other identifier that will be required for linkage]* and provide it to PopData so that they can identify your records that we request from the agencies listed above.
* PopData will use your Personal Health Number *[insert here: any other identifier that will be required for linkage]* to communicate with the agencies listed above and to identify the records that were requested and approved in this study. PopData will not use your information in any way other than as authorized by this consent form.
* Before providing your agency health records to the research team, PopData will replace your Personal Health Number *[insert here: any other identifier that will be required for linkage but subsequently removed]* with a randomly assigned number known as Study IDs that is specific to the project. **This way, the researcher will not be able to connect your responses and records to the information that was used to identify you as part of the linkage process** (i.e., your Personal Health Number; *insert others if required).*

**Where will my information be stored and analyzed?**

Your study information will be stored in two *[insert relevant number of locations]* different places as described below *[insert more locations, as required]*:

* Location 1 *([insert relevant storage location 1; e.g., UBC Hospital])*: The *[insert all relevant data to be stored at location 1]* information collected by the research team will be stored here. In this location, your information will be protected by *[insert specific security features of this location; e.g., your Personal Health Number will be stored separately from your survey responses]*.
* Location 2 (PopData): As explained, we will provide your Personal Health Number *[insert more, if required]* to PopData so that they can undertake the data linkage process. The research team will usually access and analyze the linked study data (including your survey responses and your requested and approved agency records) on Population Data BC’s Secure Research Environment (SRE), unless otherwise approved. Information is stored on the SRE in accordance with strict government security standards. The SRE is a secure central server accessible only via an encrypted Virtual Private Network (VPN) through a firewall.

**What will you do with the results of the study?**

The main study findings will be published in *[insert types of publication materials and students should indicate if the results will be reported in a graduate thesis; i.e., academic journal articles]*.Your identity will not be available in any reports of the completed study. If you would like a copy of the published results, you will be able to contact *[insert contact here].*

**What are the potential risks and/or benefits to the study?**

There are no direct benefits to you for taking part in this study *[please insert benefits if applicable].* However, in the future, others may benefit from what we learn in this study. We do not think there is anything in this study that could harm you or be bad for you *[please insert risks, if applicable]*.

**How will my identity be protected?**

Your confidentiality will be respected. If you choose to participate in this study, information that discloses your identity will only be used as described in this consent form, unless required by law. We will follow strict guidelines designed to maximize the privacy and security of your information, which are described in more detail in the “***How will data linkage happen?”*** and ***“Where will my information be stored?”*** sections. In addition to this, the collection, use and disclosure of your information will be held in strict accordance with the *F*reedom of Information and Protection of Privacy Act and/or the Personal Information Protection Act.

**Can I withdraw from the study?**

You may withdraw at any time *[insert if applicable: without any impact to your medical care]* and may choose between two types of withdrawal:

a) Withdraw but allow the research team to retain data already collected about you. No additional data will be collected about you

b) Withdraw and request all data already collected about you be destroyed. No additional data will be collected about you.

If you choose to withdraw all your data AFTER your data has been de-identified and merged with data from the other providers noted above, then the research team will inform PopData of your withdrawal. PopData will then give the research team information about you that would allow the research team to **identify all your records (including those from the agencies noted in this consent)** in the combined data. The research team will then remove the data collected by them within the combined data.

**Will I be paid for taking part in this research study?**

We will not pay you for the time you take to be in this study *[insert response or payment details, as applicable to the study]*.

**Who can I contact if I have questions or concerns about the study?**

If you have any questions about this study, you can contact *[Insert Contact]* at *[Insert Phone and Email]* or *[Insert Second Contact, if applicable]*. By signing this form, you do not give up any of your legal rights and you do not release the study team, participating institutions, or anyone else from their legal and professional duties.

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598.

**Participant Consent and Signature Page**

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to withdraw from the study at any time without giving a reason and without any negative impact on your *[for example, employment, class standing, access to further services from the community centre, day care, etc.]*”.

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have had enough time to think about the information provided.
* I have been able to ask for advice if needed.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes as described in this consent form.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I understand that I may request to have the information about me deleted from the study should I decide to withdraw.
* I authorize access to my health records as described in this consent form.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.
* I understand that there is no guarantee that this study will provide any benefits to me.
* I understand that once the study team sends the data they collected about me to Population Data BC for linking to my agency health records, my data will be identified using only final study IDs created by PopData (ie. The data will be de-identified).
* *[Insert any other research specific clauses that may be important to reiterate.]*

**Future Contact**

We may conduct other research projects related to *[insert: disease]* in the future which may require participant recruitment. May we contact you should these opportunities arise?

* Yes. You may contact me in the future regarding other studies.
* No. I do not wish to be contacted for other studies.

I will receive a signed copy of this consent form for my own records.

**Phase 1: *[insert type of study]*** - I consent to participate in this study.

*“Participant’s Signature” should be replaced with “Participant’s or Substitute Decision-maker’s Signature” if third party consent may be obtained from a legally authorized representative.*

Participant’s (or guardian’s) Signature Printed name Date

Signature of Person Printed name Study Role Date

Obtaining Consent

**Phase 2: Health Records Data Linkage** - I consent to participate in this study.

*“Participant’s Signature” should be replaced with “Participant’s or Substitute Decision-maker’s Signature” if third party consent may be obtained from a legally authorized representative.*

Participant’s (or guardian’s) Signature Printed name Date

Signature of Person Printed name Study Role Date

Obtaining Consent

**GUIDELINES**

Appendix I

*Links to REB sites providing guidance notes, policies, and/or forms for UBC-affiliated, SFU, and BC regional health authority REBs/RRC*

UBC-affiliated REBs

 [BC Cancer REB](http://www.bccancer.bc.ca/RES/REB/default.htBCCA) (BC CANCER REB)

#  [Children’s & Women’s REB](http://www.cfri.ca/research-support/reb/policies) (C&W REB)

 [Providence Health Care REB](http://www.providenceresearch.ca/research-ethics.html) (PHC REB)

UBC [Behavioural REB](file:///%5C%5Cgilbert%5Cshoebox%5CAgreements%2C%20Forms%20and%20Applications%5CConsent%20Forms%5CBehavioural%20REB) (BREB) - <https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-application>

[Simon Fraser University ORE and REB](http://www.sfu.ca/ore.html) (SFU ORE and REB)

[Fraser Health REB](http://research.fraserhealth.ca/approvals_%26_ethics/ethical_review/research_ethics) (FH REB)

[Interior Health REB](http://www.interiorhealth.ca/AboutUs/ResearchandEthics/Pages/REB.aspx) (IH REB)

[Northern Health Research Review Committee](http://www.northernhealth.ca/YourHealth/ResearchandEvaluation/ResearchEthicsNHResearchReviewCommittee.aspx) (NH RRC)

[Vancouver Island Health Authority REB](http://www.viha.ca/rnd/research_ethics/) (VIHA REB)

Appendix II

*General style and formatting guidelines for consent forms*

1. Consent forms should be written at a Grade 7 level of understanding.

 In Microsoft Word, you can display the Flesch-Kincaid Grade Level Score by clicking on “Spelling and Grammar” in your tool bar. If the option to check for readability statistics is not viewable, ensure it is enabled. In Word 2013: Click the File tab, and then click Options. Click Proofing. Ensure “🗹 Show readability statistics” is selected.

1. Type size: no smaller than the type on this page (12 point).
2. Improve readability by using headings, short paragraphs, and spaces between paragraphs.
3. Use plain language; explain medical terms and jargon. Use non-scientific terminology. For assistance with finding lay language substitutes, refer to the Canadian Cancer Society Glossary of Terms: <http://info.cancer.ca/glossary/>
4. Acronyms should be avoided. If they must be used, they should be written out the first time they appear, e.g., Peculiar Acronym for General Use (PAGU).
5. Number the pages in the following manner: “1 of 3”, “2 of 3”, “3 of 3,” etc.
6. Include a footer ON EACH PAGE with the version number and date. Also include a brief reference to the study such as the protocol number or REB number or nickname of the study.
7. All information required by the participant must be included in the informed consent form, with the exception of ancillary drug information sheets, if applicable.
8. The consent form submitted for review should be in its final form and on letterhead (as it will be seen by the participant).
9. Spelling, grammar and formatting must be corrected before submission to the REB.
10. Use second person pronouns for the participant information part of the consent form (you/your). Use first person pronoun (“I”) only for the final Participant Consent portion of the form.