**Database Creation for Research Use - Consent Form Outline**

Title of database

Principal investigator, co-investigator, sponsor, emergency contact

1. **Invitation**
   1. Why is this particular individual being contacted?
   2. Where did you get their contact information?
2. **Your participation is voluntary**

Your participation is voluntary. You have the right to refuse to participate in this research database. If you decide to participate, you may still choose to withdraw from the database at any time without any negative consequences to the medical care, education, or other servicesto which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your *[insert health care provider]* between being a patient and being a database participant. As a patient, all procedures and treatments are carried out for your benefit only according to standard accepted practice. As a database participant you and your *[insert health care provider]* also must take into account the requirements for the database. These may include the collection of information about you, your health and/or your preferences directly from you, a survey, procedures or other medical records. Taking part in the database may require the disclosure of your information for use in other research projects. This consent form describes the procedures that are being carried out for the purposes of creating this database. Please review the consent document carefully when deciding whether or not you wish to be part of the database and sign this consent form only if you accept being a database participant.

If you wish to participate in this database, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

1. **Background**

a. Brief information about disease

b. Description about knowledge gaps

c. Description of data gaps (you should be able to tie this in with the purpose of creating the database)

1. **Who is involved in the creation of this database? (Includes conflict of interest disclosure)**

a. Individuals involved and their affiliation. Include conflict of interest disclosure.

b. Sponsor and Funder

- provide statement about what contractual agreement is in place. What will be provided to funder? How will the funder be involved?

***[For all other REBs, the conflict of interest statement is required if applicable. Insert:***

The Principal Investigator [insert database personnel and/or institution] has received financial compensation from the sponsor [name the sponsor] for the work required in developing or creating this database and/or for providing advice on the design of the database/travel expenses/etc. Financial compensation to researchers for conducting the activities related to the database is associated with obligations defined in a signed contractual agreement between the researchers and the sponsor. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.]

c. Database Data Steward

- provide statement of who the data steward is and their responsibilities. (Will they review and approve applications to use database data?)

1. **What is the purpose of this database?**

a. Statement of why you are creating this database

b. Statement of how the data in the database will be used (Current research? Future research? Possible linkage to admin data? What type of research can the data be used for?)

1. **Information about the database**

**DATA**

a. What specific data is included in the database? (Append a complete list of database variables to this consent form)

b. How are the variables in the database collected? (Clinical/laboratory visit results? Sample Collection? EMR?....)

c. Is the collection of personal information collected under FIPPA or PIPA?

**LOCATION AND STORAGE**

* 1. Where is the database housed and the data stored?
  2. Will data leave this location? If so, where will it be transferred? (If data linkage will occur, make a note here that data linkage will be discussed in a separate section below).
  3. If relevant, where are biological samples stored?
  4. If relevant, will samples leave this location? If so, where will it be transferred?

**DATA SECURITY**

1. Description of location security
2. Description of computer security
3. Will Identifiers be separated from the data? If so, where will the identifiers be stored?
4. If relevant, how will the biological samples be identified/labeled?
5. Who has access to identifiers?
6. Who has access to the data?

**DATA MANAGEMENT AND ACCESS**

1. Description of process for requesting data in the database

- Who reviews?

- Who approves?

1. Description of how database data will be accessed by researchers and database team.

Who will have direct access to the whole database?

- Will researchers/staff of approved applications be able to access all database data or only ones that have been approved and that are relevant?

- Who will pull the approved data from the database for research use?

- Will the data be made available on a CD? USB? (encrypted?) Or will approved staff/researchers have VPN access

- Will the data be accessible outside of Canada?

1. Description of how long data will be held in the database
2. Description of data destruction process when the database “ends”

- What will happen to the data?

- e.g. What happens if the “PI” moves to a different position?

1. Description of what happens to the data in the database if a person withdraws consent

*[Include this note:*

You may withdraw at any time without any impact to your medical care and may choose between two types of withdrawal:

a) Withdraw but allow the database 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.

Further details about the withdrawal process will be discussed in section 12 of this consent document.  *]*

1. Statement that each study using the database data will go through a separate application, review and approval process and in cases of linkage studies, will get approval from each individual data steward.
2. **What does participating in the database involve?**

a. Sample Collection - Will you be collecting samples and lab results? If so,

- Where will the collection take place?

- How often will the samples be collected (If collection will take place at different phases, discuss what happens in each phase.)

- For what time period will the samples be retained? (If collection will take place at different phases, discuss what happens in each phase.)

- What type of samples and how will these samples be collected?

- Will identified/de-identified samples be used for future research? If so, will it be linked to other data?

b. Data Linkage – Will data from the database potentially be linked to administrative health data for future studies? If so,

- Will future projects potentially require data linkage?

- What types of data can this project be linked to?

- What identifiers will be sent out of the database for linkage purposes? Who will do the linkage?

- Where will linked data be stored?

Clinicians and researchers may submit a request to use the database data for research purposes in future studies. These studies may involve linking a copy of some data in the database to a copy of other health data held by various agencies. These requests will be reviewed by all the agencies involved including this database’s data steward. With your specific consent to allow the use of your database data for future research involving data linkage, we ask to link a copy of the data collected in this database to a copy of some of your records from the agencies described below. Please see the next section for more information about the data linkage process. If you allow us and if future research projects receive approval from all the agencies or registries involved, we will link a copy of the data collected about you in the database to the following data sources, depending on the research study, to help answer the research questions of each study: ***[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]* on 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 a copy of your data in this database to a copy of the information about you that is requested from the agencies described above, we will follow strict guidelines designed to maximize the privacy and security of your information. 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 any future studies will include the following procedures:

* Your Personal Health Number *[insert here: any other identifier that will be required for linkage]* will be provided to PopData so that they can identify your records 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 each study. PopData will not use your information in any way other than as authorized by this consent form.
* Before providing a copy of your data from this database and other agencies 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, researchers will not be able to connect your data 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 linked information be stored?**

Once a copy of your data from the database has been linked to the copy of your data from other agencies as approved for each study, this information will be stored in the location described below:

* 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 for each approved project. Once approved, the research team will access and analyze the approved linked data on Population Data BC’s Secure Research Environment (SRE). 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.

1. **What are my responsibilities?**
   1. List database participant responsibilities if any.
2. **What are the possible risks, harms and discomforts?**
   1. If relevant, list harms or discomforts associated with each sample or laboratory collection. Specify how these can be minimized.
   2. Privacy risk – Specify how this risk is minimized. (e.g. Identifiers separated from actual data, Specific personnel has access to the data, encryption, firewall)

*[Insert the following if gene database:* In addition to the risks of physical harms outlined in this consent form, there are also possible non-physical risks associated with taking part in this database. For example, disclosure of genetic or tissue marker research data could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released is estimated to be small. *]*

1. **What are the potential benefits of participating?**

You will not receive direct benefits from participating in this database. However, we hope that the information learned from studies using data from this database can be used to benefit other people with a similar disease.

**11. What if new information becomes available that may affect my decision to participate?**

You will be advised *[Insert here: individual or team who will advise participants]* of any new information that becomes available that may affect your willingness to remain in this database.

**12. What happens if I decide to withdraw my consent to participate?**

1. Restate what will happen to:

* Samples, if relevant
* Data already collected in the database
* Future collection of data for the database
* Data collected and regulated by Health Canada or the US FDA

*Include this note:*

You may withdraw at any time without any impact to your medical care and may choose between two types of withdrawal:

a) Withdraw but allow the database 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 database team will inform PopData of your withdrawal. PopData will then give the database team information about you that would allow the database team to **identify all your records (including those from the agencies noted in this consent)** in the combined data. The database team will then remove the data collected by them within the combined data.

**13. How will my taking part in this registry be kept confidential?**

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Data Stewards, the Investigator or his or her designate, by representatives of *[insert here, if relevant, the name of the sponsoring company or cooperative group conducting the database,]* Health Canada, *[insert here, if relevant, the U.S. Food and Drug Administration,]* and *[insert name of your REB]* for the purpose of monitoring the research (e.g. auditing for compliance). No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

If you provide your consent to link a copy of your database data to a copy of your data from other agencies, for each approved research study, the identifier list described above will be sent to Popdata via a secure file transfer program. The copy of your data in the database that has been approved for each study will be sent in a separate file to PopData using a secure file transfer program and this data will only be identified by a study specific unique study ID. PopData will link the copy of your database data to a copy of your data from the other agencies, as approved for in each study, and replace all identifiers with a final study ID created by PopData in order to protect your identity . At this point, all information about you will only be identified by the final study ID. The linked data about you and the final study ID will usually be stored and accessed by the research team on the Secure Research Environment at PopData, unless otherwise approved. 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 above. In addition to this, all 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.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the privacy office of the institution where the research is being conducted.

**14. What happens if something goes wrong?**

By signing this form, you do not give up any of your legal rights and you do not release the database team, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this database, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and/or by the database sponsor *[insert name of sponsor]*.

**15. What will participating in the database cost me? (Reimbursement/Remuneration)**

**16. Who do I contact if I have questions about the database?**

If you have any questions or desire further information about this database before or during participation, or if you experience any adverse effects (database attack?), you can contact *[insert database data steward or his/her representative] at (xxx) xxx-xxxx, ext. xxxx.*

***[For BC CANCER REB*** *studies, insert:*

In the event of an injury related to the activities surrounding this database, please speak to the database data steward or representative (indicated above) or (after hours) call the BC CANCER centre nearest you and ask for this database’s data steward or representative, if he or she is not available, your usual oncologist or the oncologist on call.

Or, you can speak to the Head of *[insert program name, e.g. the Systemic Therapy or Radiation Therapy]* Program of the BC Cancer. That person can be reached at *(xxx) xxx-xxxx.*

**17. Who do I contact if I have any questions or concerns about my rights as a participant?**

*[For UBC-affiliated REBs (BC CANCER REB, C&W REB, PHC REB, UBC CREB), insert:*

If you have any concerns or complaints about your rights as a database participant and/or your experiences while participating in this database, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).*]*

*[For FH RE, insert:*

If you have any concerns about your rights as a database participant and/or your experiences while participating in this database, contact the Fraser Health Research Ethics Board co-Chair by calling 604-587-4681.*]*

*[For IH REB, insert:*

If you have any concerns about your rights as a database participant and/or your experiences while participating in the database, we would be interested in hearing from you. Please feel free to contact the Chair of the Interior Health Research Ethics Board at (250) 870-4602 with your concerns.*]*

*[For VIHA REB, insert:*

If you have any concerns about your rights as a database participant and/or your experiences while participating in this database, or if you wish to verify the ethical approval of this database, you may contact Karen Medler, Research Ethics Coordinator, or Dr. Marie-Térèse Little, Chair of the Clinical Research Ethics Board for the Vancouver Island Health Authority (250-370-8620).*]*

**18. Signatures**

a. Please have a separate check box/signature line to consent for taking part in the database and database data to be used in any future research (ie. research involving patient contact and data linkage type research or just research involving patient contact)

*[Insert full database title]*

**Database Participant Consent**

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.
* I understand that my participation in this database is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this database 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 database should I decide to end my participation in the database.
* 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 database will provide any benefits to me.
* I understand that once the database 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.]*

**Consent to Future Contact**

Other researchers may conduct research projects related to *[insert: disease/drug/device info]* 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 future studies.

*[Where participants who lack capacity are capable of assent, insert:*

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.*]*

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

**Consent to participate in this database** - I consent to participate in this database.

*“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 Signature Printed name Date

Signature of Person Printed name Database Role Date

Obtaining Consent

**Consent to Data Linkage** - I consent to have my information from the database linked to my data held by other agencies for future research projects.

*“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 Signature Printed name Date

Signature of Person Printed name Database Role Date

Obtaining Consent

***[Where*** *applicable include the following elements:*

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the participant assisted during the consent process in one of ways listed below?

□ Yes □ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check “no”.]

If yes, please check the relevant box and complete the signature space below:

□ The consent form was read to the participant, and the person signing below attests that the database was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read ).

□ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

Signature of Person Assisting Printed Name Date

in the Consent Discussion

***[Witness signature is optional. See comments, insert as required]***

**Witness Signature**

Witness Signature Printed name Date

**Investigator Signature**

Investigator Signature Printed name Date

My signature above signifies that the database has been reviewed with the database participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.