Registry Consent form Template Instructions

\*\*Before you begin

* Sample wording is in regular font. Please **edit** to be applicable to your registry.
* Required wording is highlighted in yellow.
* If applicable to your registry, required wording is highlighted in blue otherwise remove text.
* <Purple text> should be text completed by registry team.
* Author comment bubbles are CREB guidance to Registry team.
* Form should be written at a reading level appropriate for the target audience.
* For participants from the general population:
  + Use plain language; explain medical terms and jargon. Use non-scientific terminology.
* Text size: no smaller than 12 point.
* Define all acronyms and abbreviations when they first appear. Limit number of acronyms used.
* Once you have completed your draft, please:
  + Delete this instruction page.
  + Remove highlighting from text.
  + Remove author comments.

<Insert Institutional Logo(s)>

**Registry Participant Information and Consent Form**

**<Insert Title of Registry>**

|  |  |
| --- | --- |
| Registry Custodian: | Name, (For Dr title, define if M.D. or PhD)  Department  Institution/centre  Contact information |
|  | |
| Registry Site Lead: | Name, (For Dr title, define if M.D. or PhD)  Department  Institution/centre  Contact information |

Sponsor(s) / Funder:

Registry Team Contact information:

**1. Invitation**

In addition to the main study entitled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_, you are being invited to take part in an optional registry. Participation in this registry is optional and will not impact your participation in the main study. If you decide to participate, you may withdraw your participation from the registry and remain a participant in the main study.

You are being invited to take part in this registry because <define target population>

A registry will receive, store, processes data and then distribute data to researchers for the purpose of future research.

**2. Your participation is voluntary**

Your participation is voluntary. You have the right to refuse the storage of your data in this registry. This decision will not negatively impact your care.

Please review the consent document carefully when deciding whether or not you wish to be part of the registry and sign this consent only if you agree to participate in this registry.

**3. Who is conducting this registry?**

<Name of registry> is managed by a custodian: <Name, Institution>, and it is sponsored by <sponsor name(s)>. This means that <Name>, has received funding from the sponsor to support this registry.

The registry custodian and/or site lead <list individuals with conflicts of interest>and/or <institution> has received financial compensation from the sponsor <insert name the sponsor> for the work required to establish this registry and/or for providing advice on the design of the registry. Financial compensation to registry team is associated with obligations defined in a contract between the registry team, <institution> and the sponsor. The individuals listed in this section must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the registry team.

**4. What is the purpose of the registry?**

The purpose is to create a registry for future research purposes in area of <Enter disease type or particular field of study>

**5. Background**

Researchers in the area of <insert relevant condition>, will be provided data from the <Name of Registry> to conduct their own studies. As research is always progressing, it is unknown at this time what future research will be done on your data but some of these studies may lead to new products, such as drugs or tests.

Researchers will only be given access to coded data and will not know your identity. Coded means personal identifying info such as your name will not be used, instead a code or unique number will be use to label your data.

The registry will be enrolling \_\_\_\_\_participants for the entire registry and are targeting enrolling \_\_\_\_participants from BC sites.

**6. Who can participate in this registry?**

You may be able to participate in this registry if:

**7. Who should not participate in this registry?**

You will not be eligible to participate in this registry if:

**8. What does registry participation involve?**

If you agree to take part in this registry, the procedures you can expect will include the following:

**Data collected for the registry**

Data collected will be stored in a coded manner, details related to confidentiality are set out in a later section.

Questionnaires:

You will be asked to complete questionnaires on \_\_\_\_\_\_\_ <state topics the questionnaires will be cover; recommend not listing questionnaire names>. You will be asked to complete questionnaires via <Describe method of administration>. You do not have to answer any questions that you are uncomfortable answering.

Medical Records:

There is no change in your regular care, we are asking your permission to extract your medical record data and enter it in the registry. The following will collected: <summarize what data will be collected>. Lab results from your routine care \_\_\_\_\_\_\_\_\_<indicate eg bloodwork, MRI> results will also be collected and stored in the registry. <Add timeframe for data collection-ie how long data will be extracted from records>

Imaging:

MRI scans and X-ray images taken during your routine care will also be stored in the registry and appropriate steps will be taken to remove information that will identify you from the images.

**Collection timepoints**:

< Describe the frequency of data collection, time needed per collection point, and length of collection period.>

**9. Registry Information**

Duration of storage:

The data will be stored securely for \_\_\_ years.

OR

The data will be stored indefinitely

Security of data within registry:

The registry will be managed according to strict privacy and security standards established by <name institute/organization>

Access to Registry Data:

Researchers can request to study the data stored in the registry. These researchers could be from UBC or from the custodian’s institution, as well as from other universities/academic institutes, hospitals/health institutions, non-profit foundations, or even for-profit companies (e.g. biotechnology, diagnostic, medical device, pharmaceutical or technology companies).

All Canadian researchers requesting the use of your registry data will need to obtain research ethics approval to be allowed access to your data.

Your data may be shared with researchers outside of Canada and are thus not required to comply with Canadian research ethics requirements but must follow their respective country’s research ethics requirements. Please note that some countries **may not** require ethics approval or oversight for the research that is conducted on your data.

Researcher requests to access your data will be reviewed by \_\_\_\_\_\_\_\_<indicate governance in plain language, ensure that it matches Protocols>. \_\_\_\_\_\_\_\_ will verify that the proposed research use conforms with the objectives of the registry and is in line with what you have consented to.

Researchers who would like to do research using your data will not attempt to re-identify you from the data. Researchers will not be permitted to use or store your data indefinitely. Researchers may be charged a fee to help cover some of the costs of storage, release, and overall operation of the Registry.

**10. What are the possible risks, harms and discomforts?**

Privacy breach

When you donate your data to the registry, there is a possibility of a privacy breach. The risk of your registry data being accidentally released or accessed without permission is estimated to be <insert risk level as appropriate>.

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

There may not be direct benefit to you from taking part in this registry. It is hoped that the information learned from research conducted on data obtained by the registry can be used in the future to benefit other people with a similar disease or condition.

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

If you decide to participate, you may still choose to withdraw from the registry at any time without giving reasons and without any negative consequences to the medical care, education, or other servicesto which you are entitled or are presently receiving.

If you choose to enter the registry and then decide to withdraw at a later time, you have the right to request the withdrawal of your data collected during the registry. This request will be respected to the greatest extent possible.

Please note however that there may be exceptions where the data will not be able to be withdrawn. For example:

* If the data is no longer identifiable (meaning it cannot be linked in any way back to your identity), or
* If the data has been merged with other data, or
* If the data have been distributed to researchers it will not be recalled from those researchers.

If you would like to request the withdrawal of your data, please let the registry team know. The registry team will ask you how you would like to handle your remaining data, and you may choose to have your data removed OR kept by the team if you wish.

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

Your confidentiality will be respected. However, registry records or other source records identifying you may be inspected in the presence of the registry team and by representatives, <Insert name of Research ethics board> Research Ethics Board and <insert if applicable, the name of the sponsoring company conducting the registry>for the purpose of monitoring the registry. 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.

You will be assigned a unique registry number (code) as a participant in this registry. This number will not include any personal information that could identify you (e.g., your Personal Health Number, etc.). Only this number will be used on any data collected about you during the course of this registry, so that your identity will be kept confidential. Information that contains your identity will remain only with the registry custodian/registry site lead and/or designate. The list that matches your name to the unique registry number will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected in Canada by federal and provincial laws that are intended to require safeguards to ensure that your privacy and confidentiality is respected.

The registry may send your data to other countries. Any registry related data, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, dealing with protection of information may not be as strict as in Canada. However, all registry related data, that might be transferred outside of Canada will be coded before leaving the registry site.

By signing this consent form, you are consenting to the transfer of your information to entities located outside of Canada:

* <List Entity name, Country name>

**Open Access**

Researchers may be required to deposit de-identified research data into publicly accessible location at the time of publication. This can enhance the transparency of the research data and allow for external validation. This data could include \_\_\_\_\_\_\_\_\_\_. At no time will identifying information, such as name, birth date or street address be included in such data. The extent of the risk of you being identified through public data is unknown, but currently appears to be low. Once data is made publicly available, you will not be able to withdraw the data.

**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 registry custodian or site lead or registry team, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of the \_\_\_\_\_\_, 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 registry sponsor, \_\_\_\_\_\_\_\_\_\_ <insert name of sponsor>.

**15. What will participation cost me?**

All procedures that you will receive during your participation in this registry will be at no cost to you. You will not be paid for taking part in this registry. Future research done with your data may lead to the development of new diagnostic tests, drugs, or other medical products that may have commercial value. If it does, you will not get any payment.

Reimbursement:

**16. If I have questions about the registry, who should I speak to?**

If you have any questions or desire further information about this registry, its operations and how it will be managed, you can contact the registry team at\_\_\_\_\_\_\_\_\_\_\_\_

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

If you have any privacy concerns, concerns or complaints about your rights as a research participant and/or your experiences while participating in this registry, 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.) Please reference the application number (H\_ \_-\_ \_ \_ \_ \_) when contacting the Complaint Line so the staff can better assist you.

**18.** **Future Contact**

|  |
| --- |
| Registry Updates:  If you wish to be provided with information relevant to your consent throughout the storage and use of your data, you can provide your contact information below.  I would like to receive periodic future updates regarding the research resulting from this registry.  □ Yes □ No Initials\_\_\_\_\_\_\_\_\_\_\_  Note that if your contact information changes over the course of the registry, you must contact the team to provide updated contact information to the registry team. |
| Additional Data: The registry team may also re-contact you to ask additional questions or invite you to share additional data in the future.  □ Yes □ No Initials\_\_\_\_\_\_\_\_\_\_\_ |
| Are you interested in learning about studies conducted by Dr. \_\_\_\_\_\_\_ in the future? Note that for any future studies, a separate consent form will be provided to you for review.  □ Yes □No Initials\_\_\_\_\_\_\_\_\_\_\_ |
| I agree to be contacted in the future for the above selections.  Contact Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone Number: (\_\_\_\_\_) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**19. Optional Components of this Registry**

The following will describe optional components of the registry. A description is provided and checkboxes will be provided at the end of the consent form to allow you to opt-in for these components.

Data linkage :

In addition to the data collected above, we are asking your consent to link administrative data from < database name(s) > to be stored in the registry.

<Indicate how linkage will occur and if a personal identifier will be used for the linkage>

<Describe the timeframe of data that will be included in the linkage process>

The Registry team will provide your personal identifier: \_\_\_\_\_\_to the database custodian to link information about you related to <summarize what variables>. Limited individuals will have access to your personal identifier. Your personal identifier will be removed before any analysis of the data occurs. Linking of data will be done in a way that protects your identity and information will be transferred securely.

Linkage of information held about you will date back to \_\_\_\_\_ years before enrolling into the registry, as well as information obtained about me \_\_\_\_\_<enter timeframe>

Data linkage is optional and you can still participate in the registry even if you do not consent to data linkage.

Sharing your data with for-profit companies**:**

Sharing your coded data with for-profit companies such as pharmaceutical companies is optional. You will be asked to provide your consent below.

A for-profit company could be a pharmaceutical or a biotechnology company that wants to make a new drug or test a currently approved drug. It may also be a pharmaceutical or biotechnology company that develops new ways to treat or diagnose disease. It may also be a diagnostic company, a medical device company or a digital health technology company that develops new ways of detecting, diagnosing or monitoring a disease. There may be other for-profit companies and other uses than are set out here.

If you consent to for-profit company sharing, the custodian may receive money from the company:

* To cover the costs of preparation and shipping of your data
* To cover ongoing costs of maintaining the registry
* As part of a research collaboration with the company where the money is used to cover the research costs at the custodian’s institution for the testing and analysis of your data.

**Genetic Research on Data**

Every person has their own unique set of genes. Genes carry the information that helps to determine your characteristics. Genes are made up of a molecule called DNA; between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. These variants may or may not be harmful. Genes are passed down from parents to children, but sometimes genes can change between generations or because of other factors (e.g., environment). “Genetic research” is a type of research that studies these variants, and will hopefully provide a better understanding of the links between the genetic variants and specific diseases, and eventually develop new ways to prevent, detect and treat these diseases.

Human biological samples such as blood will not be stored, this is related to genetic data only.

Risks of Genetic research:

Canadian Federal law now prohibits anyone such as an employer or an insurer from requiring you to disclose the results of a genetic test or to take a genetic test as condition of providing services. In addition, discrimination against individuals based upon genetic characteristics is now prohibited by the Canadian Human Rights Act.

Due to rapid advances in technology and science, the potential for future use of genetic information is unknown and therefore the risks are also unknown.

Incidental (Unexpected) findings:

It is possible that research on your donated data may uncover a finding that the researchers were not looking for, such as a medical condition.

If a clinically relevant incidental finding is discovered, you have the right to know but you may choose whether or not you want to know. At the end of this consent document, you will be offered the option of being told if an incidental finding of this type is discovered. Whatever your choice is now, you may change your mind at any time by telling a member of the registry team. If you choose to know the details, you will be given information about how to proceed by the registry team.

In the event a clinically relevant finding is discovered, confirmatory testing will likely be performed, and counselling may be recommended (which may not be covered by Provincial healthcare).

**Optional components:**

**If I initialize one or more boxes below**, I agree to have my data described in this form stored (banked) for use in the following types of future studies without requiring further consent or contact from the registry team:

|  |  |
| --- | --- |
| **Initials** | **Optional Component** |
|  | Data linkage of my data with the named administrative database with data stored in the registry |
|  | I authorize the use of my data by for-profit companies such as biotechnology, diagnostic, medical device, pharmaceutical or technology companies for the company’s research studies. |
|  | Genetic Research |

**21. Signatures**

**Participant Consent**

**<Insert full Registry Name>**

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that my participation in this registry is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this registry at any time.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.
* I authorize access to my health records as described in this consent form.

I consent to participate in this registry.

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

Participant’s Signature Printed name Date

Signature of Person Printed name Registry Role Date

Obtaining Consent

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Witness Signature Printed name Date

**Incidental Findings:**

I understand that clinically relevant incidental findings may not be discovered for many months or even years following the collection of my data. If and when such findings are discovered:

□ I do NOT want to be notified about incidental findings. (*If selected, jump to signature section*).

**OR**  
□ I DO want to be notified about clinically relevant incidental findings:

|  |
| --- |
|  |
| In the event that clinically relevant incidental findings are discovered after I die: |
| □ I DO NOT want this information to be shared with my next of kin  **OR**  □ I DO want this information to be shared with my next of kin, who can decide whether or not they want to know the findings:  Next of Kin’s Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone: (\_\_\_\_\_) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I understand that I may change my decision at any time related to clinically relevant Incidental findings by contacting the registry team.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s Signature Printed name Date