**GENETIC ADDENDUM**

**Genetic Research and Long-Term Storage of Human Biological**

**Specimens**

**USE OF THIS FORM**

This form is to be used for all research that consists of:

1. Any human biological materials, such as blood samples, tissue, etc., that will be used for genetic study,

***OR***

1. Storage of biological specimens for future uses, even if genetic study is not anticipated

If both of the above uses are applicable, you must complete one addendum for the main study and another addendum for any optional sub-studies.

**TERMS**

Data: Any test results that result from any genetic research.

Specimen: Any human biological samples.

**CONSENT**

Only persons deemed *capable of giving informed consent* may be enrolled into optional biobanking substudies.

|  |  |
| --- | --- |
| **REB NUMBER:** Click here to enter text.**PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.**PRINCIPAL INVESTIGATOR:** Click here to enter text. |

PLEASE CHOOSE **ONE** OF THE FOLLOWING OPTIONS:

[ ]  Genetic analysis ***IS*** planned.

 Please complete Sections **1, 2, 3 and 4**.

[ ]  Anticipated use of acquired specimens, collected either in the current study, or within optional sub-studies, is **undetermined**.

 Please complete Sections **1, 2, 3 and 5**.

**SECTION ONE: PURPOSE AND INTENTIONS**

1. Who will maintain ownership rights of the specimens?

**Click here to enter text.**

1. Who will have access to the specimens/data?

**Click here to enter text.**

1. Explain the clinical relevance, rationale, and specific intentions of the proposed genetic analysis.

**Click here to enter text.**

1. Specimens that will be used for future unspecified purposes, please describe the anticipated uses.

**Click here to enter text.**

1. Will data/specimens be used for commercial purposes?

 [ ]  Yes [ ]  No

If **yes**, please explain.

**Click here to enter text.**

**SECTION TWO: METHODS**

1. Describe the nature of the human biological specimens that will be

 Collected (type and amount of tissue, etc.).

 **Click here to enter text.**

1. Describe the procedures involved in acquiring the specimens, as well as how they will be transported to the biobank.

**Click here to enter text.**

1. Describe how the specimens will be stored, when and how they will be destroyed.

**Click here to enter text.**

1. Describe how long the data will stored, how and when it will be destroyed.

**Click here to enter text.**

1. Describe the clinical procedures in relation to collection of the specimens, and any foreseeable risks.

**Click here to enter text.**

1. Describe any foreseeable risks in relation to the use of the data (privacy, analyses, etc.)

**Click here to enter text.**

1. Will you initiate any future contact with research participants in this study?

[ ]  Yes [ ]  No

If **yes**, please explain the purpose of initiating contact, and under what circumstances:

**Click here to enter text.**

1. Describe the participant consent process, and provide a copy of the consent form:

**Click here to enter text.**

**SECTION THREE: IDENTIFICATION**

1. How will the specimens and the generated data be identified:

 [ ]  **Identified Specimens**: Specimen samples can be identified via direct associated identifiers (name,

 health card, etc.)

 [ ]  **Identifiable specimens**: Using reasonable foreseeable means, specimen samples can be

 identified by a combination of indirect identifiers (place of residence, date of birth, or

 unique personal characteristic)

[ ]  **De-indentified/coded specimens:** Specimen samples do not contain identifiers, and are assigned a

 code whereby samples may be identified by these codes only

[ ]  **Anonymized specimens**: All identification, including the code, has been removed from specimen

 samples, not allowing future re-linkage

 [ ]  **Anonymous**: Identifiers have never been associated with specimen samples

**SECTION FOUR: GENETIC RESEARCH**

1. Please identify the following information that will be collected:

[ ]  Family History

 If so, please explain: **Click here to enter text.**

 [ ]  Race or ethnicity

 If so, please explain: **Click here to enter text.**

1. Will the result of the findings be shared with research participants? (Please note, there must be a plan for sharing results in compliance with the preferences of the participant)

 [ ]  No [ ]  Yes

**If yes:**

1. Are these procedures described in the protocol?

 [ ]  Yes [ ]  No

1. Are they described in the participant consent form?

 [ ]  Yes [ ]  No

1. Describe these procedures for the current study:

**Click here to enter text.**

1. Under exceptional circumstances, researchers may be under obligation to disclose genetic information to biological relatives of the participants. For example, genetic findings may reveal information of a serious or life-threatening diagnosis in which treatment intervention is necessary.

Do you reasonably foresee this within the context of this study?

 [ ]  Yes [ ]  No

If yes, please explain: **Click here to enter text.**

Please confirm you have included this information in the Research Ethics Application, as well as the Consent Form(s).

 [ ]  Yes [ ]  No

1. Please indicate whether a participant can withdraw from the genetic portion of the study or the optional substudy?

 [ ]  Yes [ ]  No

If no, please explain:

**Click here to enter text.**

1. Please explain how the genetic results will be protected from access by third parties (who do not have explicit consent from the participant):

**Click here to enter text.**

**SECTION FIVE: BIOBANKING AND LONG-TERM STORAGE**

1. Please identify where the biobank or repository is located?

**Click here to enter text.**

1. Please indicate the type of biobank or repository:

[ ]  Database only (no biological samples)

[ ]  Small public collection

[ ]  Large public collection

[ ]  Private not for profit sector collection

[ ]  Private for profit/commercial use collection

[ ]  Specialized collection (blood banks, forensic institutes, etc.)

1. Is access to the stored specimens or repository granted by the biobank or repository contingent upon the following:
2. REB/IRB approval

[ ]  Yes [ ]  No

1. Permission from an internal committee to ensure ethical and scientific validity

[ ]  Yes [ ]  No

1. Can specimens be retrieved, or data removed from the dataset, should a participant change their mind?

 [ ]  Yes [ ]  No

If no, please explain:

**Click here to enter text.**

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*I confirm to the best of my knowledge that the information provided above is accurate and true.*

*I agree to conduct this trial as per the Tri-Council Policy Statement (TCPS-2), the ICH Good Clinical Practice Guidelines (GCP), and all other regulatory guidance that may be applicable to this study including the Health Canada Division 5 Food & Drug regulations, Natural Health Product regulations, Division 3 Radiopharmaceutical regulations and the Health Canada Medical Device regulations, as well as all institution specific policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

**Qualified/Principal Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***