**BRUYÈRE RESEARCH ETHICS BOARD –**

**GENETIC RESEARCH & LONG-TERM STORAGE OF HUMAN BIOLOGICAL SPECIMENS**

**INSTRUCTIONS:**

This form is to be completed for research that involves:

1. the use of any human biological material such as tissue, cells, blood samples, etc., for genetic study or
2. The storage of specimens for future use, regardless of whether or not genetic study is anticipated.

If applicable to both, investigators must complete one addendum for the main study and another addendum for any optional sub-studies.

For the purposes of this document, “data” refers to the test results arising from genetic research and “specimen” refers to stored human biological samples.

No person determined to be incapable of providing consent may be enrolled into optional biobanking substudies by their substitute decision maker or power of attorney for personal care.

The specimens collected from our patients cannot be used for the creation of an immortalized cell line (i.e., specimens are used until they are depleted and no specimen may be immortalized).

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| **REB #** | **PRINCIPAL INVESTIGATOR/BRUYÈRE INVESTIGATOR** |
|  |  |
| **STUDY TITLE** |
|  |
| **Please choose one of the options below:** |
| [ ]  This addendum relates to the collection, use and  storage of specimens for which genetic analysis is  planned. Complete Sections 1, 2 and 3 below. | [ ]  This addendum relates to the collection and storage  of specimens acquired either in the current study or  in optional sub-studies for which the anticipated uses  are still undetermined. Complete Parts 1, 2 and 4  below. |
| **PART 1: Purpose and Objectives** |
| 1. Briefly outline the rationale, clinical relevance, and specific objectives of the study or the genetic analysis being proposed. For specimens being collected for future unspecified use, please describe the reasonably foreseeable uses of these samples.

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| 1. Who will have control and ownership of the data/specimens?

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

 [ ]  **Yes** [ ]  **No** If **yes**, explain:  |
| 1. Who will have access to the data/specimens? (Include academic and commercial partners, as well as legal situations that might necessitate access to data/specimens).
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| **PART 2: Procedures** |
| 1. Clearly describe the nature of the human biological specimens that will be collected (ie., type of tissue and amount etc.).
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| 1. Describe the means by which these specimens will be taken (ie., explain the procedures involved, including the transportation to the biobank).
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| 1. Describe how long these specimens will be stored and, if applicable, how and

when they will be destroyed. |
| 1. How long will data be stored and, if applicable, how and when will it be destroyed?
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| 1. Describe the reasonably foreseeable risks related to:
2. Collection of the specimens (ie., the clinical procedures)

 1. Use of data (ie., privacy breach of the outcome of any studies or analyses)
 |
| 1. Describe the identifiability of the specimens and the data generated from the collection and analyses.

Choose one of the options below: [ ]  **Identified specimens**: Donors can be identified through direct identifiers associated with the sample (ie.,  name, address, social insurance number, health card number); [ ]  **Identifiable specimens**: Donors can be identified by a combination of indirect identifiers (ie., date of birth,  place of residence, or unique personal characteristic) using reasonably foreseeable means;[ ]  **De-indentified/Coded specimens:** Identifiers are removed from samples and replaced with a code that  permits individual donors to be identified only by use of that code, access to which may be restricted;[ ]  **Anonymized specimens**: Specimens are irrevocably stripped of any means of identification and a code is not  kept to allow future re-linkage; [ ]  **Anonymous**: Information that never had identifiers associated with it. |
| 1. Will there be any future contact with participants, families or groups in this particular study?

 [ ]  **Yes** [ ]  **No** **If yes**, under what circumstances will contact be initiated, and for what purpose(s)?  |
| **PART 3: Genetic Research** |
| 1. Is information about family history being collected?

 [ ]  **Yes** [ ]  **No****If yes**,explain: |
| 1. Is information about race or ethnicity being collected?

 [ ]  **Yes**  [ ]  **No****If yes,** explain: |
| 1. Is information about race or ethnicity being collected?

 [ ]  **Yes** [ ]  **No** **If yes,** explain:  |
| 1. Does the researcher plan to inform individual participants of the results of their findings?

 [ ]  **Yes** [ ]  **No** **If yes,** researchers must develop appropriate procedures for communicating results in accordance with the  participant’s preferences or instructions.   Are these procedures described in the protocol? [ ]   **Yes** [ ]   **No** Are they described in the participant consent form? [ ]   **Yes**  [ ]   **No**  Describe these procedures for the current study:   |
| 1. Researchers may have an obligation to disclose information to biological relatives of the research participant in exceptional circumstances. This may include instances where genetic research reveals information about a serious or life-threatening condition that can be prevented or treated through intervention, even if the participant has expressed a preference against sharing information.

 Do you foresee any such obligation within the context of this study or the undetermined uses of the specimens or  data? [ ]  **Yes** [ ]  **No** **If yes**, explain:   Has this obligation been included in the REB Submission Form? [ ]  **Yes** [ ]  **No**  Has this obligation been included in the Informed Consent Form? [ ]  **Yes** [ ]  **No** |
| 1. Can a participant withdraw from the genetic portion of the study or the optional sub-study proposed?

 [ ]  **Yes** [ ]  **No** **If no**, explain:  |
| 1. How will the researcher ensure that the results of genetic testing and genetic counseling records are protected from access by third parties, e.g., insurance companies, courts, financial and other agencies, future employers, etc., without the consent of the participants?
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| **PART 4: Description of the Biobank or Long-Term Storage of Data Derived from Specimens** |
| 1. Where is the repository or biobank located?
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| 1. What type of repository or biobank is this? Please choose one:

 [ ]  small public collection  [ ]  large public collection [ ]  database only (no actual biological samples) [ ]  private for profit/commercial use collection [ ]  private not-for-profit sector collection [ ]  specialized collection (ie., forensic institutes, blood banks) |
| 1. Describe the process of consent by donors. Include a sample of the consent form or justify and explain if no form is available:
 |
| 1. Does the repository or biobank require the following prior to approving access to the stored specimens or data for a research project:

 Confirmation of REB/IRB approval? [ ]  **Yes** [ ]  **No** Permission of an internal committee to ensure ethical and scientific validity? [ ]  **Yes** [ ]  **No** No release of identifiable or reasonably re-identifiable specimens or data? [ ]  **Yes** [ ]  **No**  Can specimens be retrieved, or data removed from the dataset, should a participant [ ]  **Yes** [ ]  **No** change their mind?  **If no**, explain:   |
| **SIGNATURE SECTION** |
| **Name of PI or Bruyère Investigator:**  |
| **Signature:**  | **Date:**  |