This application is intended for the use of non-identified human biological materials (B and C below). For the use of identified or coded human biological materials, where the researcher will have access to the code, please submit the Biomedical Ethics Review Form or Secondary Use of Data Form.

The following categories, provide guidance for assessing the extent to which human biological materials could be used to identify an individual:

**A. Identified human biological materials** – the materials are labelled with a direct identifier (e.g., name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

**B. Coded human biological materials** – direct identifiers are removed from the materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).

**C. Anonymized human biological materials** – the materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

**D. Anonymous human biological materials** – the materials never had identifiers attached to them, and risk of identification of individuals is low or very low. \*Category D is exempt for REB review.

\*Rapid technological advances facilitate identification of information and make it harder to achieve anonymity. These activities may heighten risks of identification and possible stigmatization where a data set contains information about or human biological materials from a population in a small geographical area, or information about individuals with unique characteristics (e.g., uncommon field of occupational specialization, diagnosis with a very rare disease). Where the researcher seeks data linkage of two or more anonymous sets of information or human biological materials and there is a reasonable prospect that this could generate identifiable information, then REB review is required.

**Project Title:**

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| --- | --- |
| **PI:** |  |
| **Personnel:** |  |
| **Proposed Project Period:** |  |
| **Status of Funds:** |  |
| **Source of Funds:** |  |
| **Fund Reference/Grant #:** |  |

Is there any real, potential or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)?

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Is there a Material Transfer Agreement to obtain materials for the study?

□ Approved □ In Process □ Pending □ No

Does the research involve the use of biologically hazardous materials or organisms?

□ Yes □ No

What is the source of the human biological material? (Where are the materials coming from)

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Describe the original source, and if known, the privacy policies and practices of the source of materials.

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Describe the human biological materials to be used.

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Will the study involve pluripotent stem cells that have been derived from an embryonic source?

□ Yes □ No

Will the study involve pluripotent stem cells that will be transferred into humans or non-humans?

□ Yes □ No

If yes, an application must be submitted to the CIHR Stem Cell Oversight Committee (SCOC)

<https://cihr-irsc.gc.ca/e/15351.html>

What are the consent policies and practices of the source of materials?

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Briefly describe the project, its objectives and potential significance.

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Provide a description of research design and methods to be used.

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Indicate how the data collected is intended to be used (thesis, journal articles, conference presentation, reports to funders etc).

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Could the research expect to result in re-identification?

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Can the samples be traced back to an individual Indigenous donor or to an Indigenous community? If yes, describe how the researcher will seek community engagement.

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Who will have access to the human biological material once received?

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Who will have access to the original data for the proposed study?

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Describe how will the PI ensure that human biological materials are stored safely and in accordance with applicable standards, and establish appropriate physical, administrative and technical safeguards to protect human biological materials from unauthorized handling?

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Location of storage of human biological materials:

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Describe the practice and timelines for disposal of research materials:

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**Declaration by Principal Investigator (or Supervisor for student projects)**

* I confirm that the information provided in this application is complete and correct.
* I accept responsibility for the ethical conduct of this project and for the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project.
* I will comply with all policies and guidelines of the University and Health Region/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.
* I will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the REB approved application.
* I certify that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation.
* I certify that a status report will be submitted to the Research Ethics Board for consideration one month prior to the current expiry date each year the project remains open, and upon project completion.
* I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place.

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Signature of Principal Investigator Date (MM/DD/YY)