**Use protocol template:**

**Guidelines for submitting protocols involving the use of material or data from an existing bank**

In what follows, a “bank” is a searchable collection of human biological material and/or data constituted for use in future research with consent from participants. Different terminology can be used to refer to such banks: biobanks, databanks, registries, etc. A “use protocol” refers to research performed using samples and/or data from an existing bank.

In use protocols, there is no contact with patients or participants. All data or samples used during the course of the project are obtained from a bank, in a manner consistent with its rules (e.g., alignment between the study’s objective and the consent obtained from participants).

It is the responsibility of the bank’s custodians and the research team to ensure alignment between the proposed study and the bank’s objectives and rules; the McGill University Health Centre (MUHC) Research Ethics Board (REB) will not be involved in this process.

Returning results to the bank:

If the bank requires it, or if the research team plans to generate data they wish to add back to the bank for future research use (e.g., genetic testing results), please confirm that the bank is able to receive such data. If the data type falls outside the bank’s current scope, contact the bank to request a scope modification. This must be done **prior to submitting your use protocol.**

Missing samples and/or data:

In use protocols, all samples and/or data must be obtained through the bank. Should your project require human biological material and/or data that the bank does not collect, contact the bank: it might be possible for the bank to start obtaining those samples and/or data. If you need to collect additional samples and/or data yourself for your study, your project will not be considered a “use protocol.” In this case, do not use the following template.

Data linkage:

This template can be used for projects that involve obtaining samples and/or data from more than one bank, regardless of whether data linkage is planned. Note that, if linkage will be done, the level of risk of the project may increase.

All the information highlighted in the template must be included and proper formatting must be used (date and version number, pagination, cover page, etc.). Incomplete protocols will not be reviewed.

**When filling out the template:**

* Please fill in the blanks as appropriate.
* Please delete all the comment boxes before submitting.

**Please do not hesitate to contact the MUHC REB office for any questions or comments on the protocol template and/or protocol submission procedure at:** **reb@muhc.mcgill.ca****.**

**Use Protocol**

**Study Title:**

[Insert Text Here]

**Principal Investigator, affiliation:**

[Insert Text Here]

**Funding source:**

[Insert Text Here]

**BANK(S) FROM WHICH SAMPLES/DATA WILL BE OBTAINED:**

* Name, Location/MUHC Nagano number
* Name, Location/MUHC Nagano number

# Background and study rationale

Click here to enter text.

# Objectives, hypothesis and study questions

Click here to enter text.

# Study methods

* 1. Study design

Click here to enter text.

* 1. Inclusion/exclusion criteria for study population

Click here to enter text.

* 1. Data and samples used

Click here to enter text.

* 1. Sample size

Click here to enter text.

# Analysis Plan

Click here to enter text.

# Ethical considerations

* 1. Oversight

This study will be conducted in accord with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2022), as well as in respect of the requirements set out in the applicable standard operating procedures of the Research Institute of the McGill University Health Centre and of the McGill University Health Centre Research Ethics Board (MUHC REB). The research will also be conducted as per the applicable agreements with the providing banks (e.g., Material Transfer Agreement, Data Sharing Agreement, etc.).

The MUHC REB will review this study and will provide oversight at all participating institutions in the health and social services network in Québec (RSSS).

* 1. Samples and/or Data Management

Click here to enter text.

* 1. Confidentiality

Only samples and/or data relevant to this study and as outlined in this protocol will be obtained by the research team. All the samples and/or data obtained during the research project will remain confidential to the extent required by law. No attempt at reidentification of samples and/or data will be made.

* 1. Dissemination plan

The study results may be published, shared in scientific meetings, or reported in rounds. Dissemination will be carried out in a manner that limits the possibility of reidentification.

# References