**Guidelines for submitting retrospective health record research protocols**

Retrospective health record research (HRR) is research performed using data *already* documented in patients’ medical records.

The main ethical concern in this type of research is respecting the confidentiality and privacy of potential participants who do not consent directly to the use of their data. When accessing patients’ health information without consent, a privacy impact assessment (Évaluation des facteurs relatifs à la vie privée (EFVP)) is mandatory. The required form will be available in Nagano when creating a new project.

In retrospective HRR, there is no contact with patients or any participants, nor are new data collected. If you realize during the course of the project that you may want to contact patients or collect additional data, please consult the McGill University Health Centre Research Ethics Board (MUHC REB) for information on how to proceed.

The following HRR protocol template is designed to assist investigators by highlighting the necessary information required by the MUHC REB to conduct delegated review. In particular, section 5.3 must be used to justify the request for a waiver of consent.

As part of the required authorization process, this protocol may be reviewed by offices external to the REB (e.g., Research Agreements Office).

All the information highlighted in the template must be included and proper formatting used (date and version number, pagination, cover page, etc.) in the submission. Incomplete protocols will not be reviewed. Please use the template below to ensure a faster review and approval process.

**When filling out the template:**

* Please fill in the blanks as appropriate.
* Please delete all the comment boxes before submitting.
* There is no minimum/maximum length for an HRR protocol; it may be short (e.g., 3-4 pages). What is important is that it concisely includes all the information requested in the template.

**Please do not hesitate to contact the MUHC REB office with any questions or comments on the protocol template and/or protocol submission procedure at:** **reb@muhc.mcgill.ca****. For questions about the availability of anonymized patient data, please consult the RI-MUHC Data Warehouse Service (****info.ridw@muhc.mcgill.ca****).**

**Study title:**  Click here to enter text.

**Principal investigator:**  Click here to enter text.

# 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. Study population
		1. Inclusion/exclusion criteria

Click here to enter text.

* + 1. Sample size

Click here to enter text.

* 1. Period studied

Click here to enter text.

* 1. Description of data being retrieved

Click here to enter text.

* 1. Duration of the study

Click here to enter text.

# Data analysis

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# 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 operation procedures of the Research Institute of the McGill University Health Centre Research Institute and of the McGill University Health Centre Research Ethics Board. The McGill University Health Centre Research Ethics Board will review this study and will be responsible for monitoring it at all participating institutions in the health and social services network in Québec.

* 1. Confidentiality

Only data relevant to this study as outlined in this protocol will be collected by the research team. All the information collected during the research project will remain confidential and will not be used for a purpose other than to meet the objective of the study.

Patient data will be de-identified and coded. The code will be kept by the principal investigator in a password-protected digital file behind the MUHC firewall.

Patient data will be anonymized before access by the research team. No code linking patient identifiers to patient data will be given to the research team and the research team will not seek to re-identify study participants.

Data will be Click here to enter text.

* 1. Waiver of consent

For this project, individual participant consent will not be sought as per the following justification(s): Click here to enter text.

In lieu of individual informed consent of participants, authorization to access patient charts will be made official by a written agreement between the researcher and the institution that reviewed the Privacy Impact Assessment (aka *Évaluation des facteurs relatifs à la vie privée* (EFVP)), as required.

* 1. Dissemination plan

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Whenever the study results are published or shared during scientific meetings or otherwise, it will not be possible to identify the participants.

* 1. Other

Click here to enter text.

# References