**Template protocol for research projects involving the development of artificial intelligence technologies using previously collected health data**

**Instructions:**

This template has been developed for research projects that develop Artificial Intelligence (AI) technologies (e.g., new algorithm) using health data that are already available, i.e., projects in which there will be no direct contact with patients or participants and for which no new data will be collected for the sole purpose of research. Examples of applications include AI technologies for screening and triage, diagnosis, prognostication, support for decision-making, and treatment recommendation.

The data used in projects for which this template was developed must come from existing sources, such as medical health records or registries. It is the responsibility of the data’s custodians and the research team to ensure alignment between the proposed study and the rules governing the use of the data in question.

If you realize during the course of the project that you may need to contact patients or collect data from participants prospectively, please consult the McGill University Health Centre Research Ethics Board (MUHC REB) for information on how to proceed.[[1]](#footnote-2)

* All the sections of the template must be completed, addressing the detailed prompts.
* If the project has multiple objectives and different methods for each, each section of the template must be answered for each objective using clear numbering.
* Proper formatting must be used (date and version number, pagination, cover page, etc.). Incomplete protocols will not be reviewed and will be returned to you.

**When filling out the template:**

* Please fill in the blanks as appropriate.
* Please delete all the comment boxes and instructions before submission.
* There is no minimum/maximum length for a study protocol: what is important is that it concisely includes all the information requested in the template. Research teams can add additional information they deem relevant.

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

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

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

**Co-investigator(s):** Click here to enter text.

**Funding and support:** 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 population

		1. Inclusion/exclusion criteria

Click here to enter text.

* + 1. Sample size

Click here to enter text.

* 1. Description of data being retrieved and sourcing

Click here to enter text.

* 1. Study design
		1. Data characteristics and pre-processing

Click here to enter text.

* + 1. AI technology used

Click here to enter text.

* + 1. Model choice

Click here to enter text.

* + 1. Training and training task

Click here to enter text.

* + 1. Evaluation

Click here to enter text.

* + 1. Hyperparameter tuning

Click here to enter text.

# Data Analysis/Evaluation

* 1. Explainability/Transparency

Click here to enter text.

* 1. Bias and risk assessment

Click here to enter text.

* 1. Metrics

Click here to enter text.

* 1. Validation

Click here to enter text.

# Ethical Considerations

* 1. Oversight

This study will be conducted in accordance 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).

* 1. Risks

Click here to enter text.

* 1. Monitoring

Click here to enter text.

* 1. Confidentiality and protection of data

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 to the extent required and provided by law.

Participant data will be stripped of identifiers and coded. The code will be kept by the principal investigator in a password protected digital file behind the MUHC firewall. Keeping coded data is required because Click here to enter text.

OR

Participant data will be anonymized. No code linking participant identifiers to participant data will be kept and it will not be possible to identify participants.

OR

Anonymized participant data are available and will be used.

* + 1. Ownership duration and retention policies

Click here to enter text.

* 1. Informed consent

Informed consent has been obtained by Click here to enter text.

OR

For this project, individual participant consent will not be sought based on 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 by law.

* 1. Anticipated uses of results

Click here to enter text.

* 1. Conflicts of interests

One or more real or perceived conflict(s) of interest are present in this project. These conflicts have been disclosed as required by institutional policies, and a management plan has been submitted for review by the MUHC REB. Any changes will be promptly disclosed as applicable.

OR

No real or perceived conflict of interest exists for this project. Any changes will be promptly disclosed as required by institutional policies, and a management plan will be submitted for review by the MUHC REB.

* 1. Dissemination plan
	Click here to enter text.

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

* 1. Intellectual property/Commercialization

Click here to enter text.

* 1. Other

Click here to enter text.

# Expertise & Experience of the Research Team

Click here to enter text.

# References

1. For projects that collect data prospectively, the template could be used to help identify the supplementary information that would have to be provided to the REB in addition to the usual information about recruitment, consent, study procedures, and related matters. [↑](#footnote-ref-2)