

<b>TITLE</b>	<b>301: Research Submission Requirements</b>
<b>SCOPE</b>	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
<b>APPROVAL AUTHORITY</b>	Ethics Director
<b>EFFECTIVE DATE</b>	April 2024

## 1.0 PURPOSE

This standard operating procedure (SOP) describes the HREB submission requirements. This SOP applies to all submissions including, but not limited to: applications for initial review of health research, amendments or changes to approved research and any new information.

## 2.0 DEFINITIONS

See the Glossary of Terms.

## 3.0 RESPONSIBILITIES

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

## 4.0 PROCEDURE

HREB members must rely on the documentation provided by the Researcher for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

The HREB is supported by administrative procedures that ensure that HREB members have adequate time for the assessment of the proposed research and that they receive the materials that allow them to adequately assess whether the research submission meets the criteria for HREB approval.

The requirements for HREB submissions will be available to all Researchers. The REO Personnel are responsible for maintaining and disseminating this information to Researchers.

HREB applications will be scheduled for HREB review following confirmation by REO Personnel that the application is complete. Incomplete submissions will be returned to researchers by REO personnel.

## 4.1 Submission Requirements

- 4.1.1** Submission requirements for new applications are outlined in the HREB Application Form and the accompanying Guidance Document. Applications will be submitted via the Researcher Portal online system.
- 4.1.2** All sections of the HREB Application Form, including all required accompanying documentation, must be completed.
- 4.1.3** REO Personnel will review each application for completeness. If there are elements missing, the investigator will be notified by REO Personnel, and applications will be returned to the researcher for completion.
- 4.1.4** Upon receipt of a complete application, REO personnel will assign the application to the applicable review committee. For full board review, the application will be assigned to the next applicable HREB meeting using the deadlines posted on the HREA website. Delegated reviews will be assigned as outlined in the Delegated Review SOP #402.
- 4.1.5** The HREB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight.
- 4.1.6** **Research Requirements:** The research question and methodology must be written in sufficient detail to permit evaluation of the merit of the project. The research will include all of the required elements applicable to the research such as, but not limited to:
- research rationale and objectives;
  - design and detailed description of methodology;
  - eligibility criteria, description of the study population;
  - recruitment and consent process;
  - research interventions;
  - treatment allocation (if applicable);
  - primary and secondary outcome measures;
  - assessment of safety;
  - sample size justification;
  - data analysis;
  - data monitoring; and
  - data management.

## 4.2 Deadlines

- 4.2.1** Application deadlines for submission to the HREB and the meeting timelines will be provided on the HREA's publicly accessible website.

### 4.3 HREB Review Fee

**4.3.1** An administrative review fee shall be levied for all industry-sponsored research studies submitted for HREB review. An additional fee will be charged for annual renewals, as well as for amendments requiring HREB review, for all industry-sponsored and for-profit studies. Details regarding fees will be posted on the HREA website.

Questions regarding payment details may be directed to REO Personnel.

### 5.0 REFERENCES

Memorial University Researcher Portal: [Home - MEMORIAL RESEARCHER PORTAL \(mun.ca\)](https://mun.ca)

Health Research Ethics Authority Website: [Health Research Ethics Authority HREA](https://hrea.ca)