

## SOP 301.001

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| <b>Title</b>          | <b>REB Submission Requirements and Document Review</b> |
| <b>SOP Code</b>       | 301.001                                                |
| <b>Effective Date</b> |                                                        |

### Site Approvals

| <b>Name and Title</b> | <b>Signature</b> | <b>Date<br/>dd/mm/yyyy</b> |
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### 1.0 PURPOSE

This standard operating procedure (SOP) describes Research Ethics Board (REB) submission requirements and document review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research, renewal applications for ongoing research and completion reports.

### 2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

### 3.0 RESPONSIBILITIES

REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

### 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURE

REB 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 REB is supported by administrative procedures that ensure that REB members not only have adequate time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB approval.

The requirements for REB submissions are made available to all Researchers. The REB Office Personnel are responsible for maintaining and disseminating this information to Researchers.

### 5.1 Submission Requirements

5.1.1 The required documents, format and submission procedures are outlined on the REB's website. These may include:

- REB application form,
- Continuing Review form,
- Amendment and/or Administrative Change form,
- Unanticipated and Adverse Event Reporting form,
- Research Completion form.

5.1.2 The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;

5.1.3 The research question and methodology is written in sufficient detail to permit evaluation of the scientific or scholarly merit of the project. The research should 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 population to be studied,
- Recruitment and consent process,
- Research interventions,
- Primary and secondary outcomes,
- Sample size justification,
- Data analysis.

## 5.2 Document Review Procedures

- 5.2.1 A unique number is assigned to each submission at the time of the receipt of the application. REB Office Personnel screens the submission for overall completeness;
- 5.2.2 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the REB Office Personnel will follow up with the Researcher and/or alternate contact to request the required information for inclusion with the submission;
- 5.2.3 Upon receipt of a complete submission, the responsible REB Office Personnel identifies any outstanding items that will be required to issue approval, as applicable;
- 5.2.4 For submissions requiring Full Board review, the REB Office Personnel posts the submission to the agenda of the next Full Board meeting. Primary and secondary reviewers are assigned once the agenda is complete, if applicable;
- 5.2.5 For submissions reviewed via delegated review procedures, the REB Chair or designee assigns a reviewer(s) and sends the research to that (those) reviewer(s).

## 6.0 REFERENCES

See References.

## 7.0 REVISION HISTORY

| SOP Code   | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP301.001 |                | Original version   |
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