

SOP Title:	REB Submission Requirements and Administrative Review		
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Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board (REB) submission requirements and the administrative review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research and any new information.

2.0 POLICY STATEMENT

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.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

5.0 PROCEDURES

5.1 Submission Requirements

5.1.1 The required documents, format and submission procedures are outlined on the REB's website and on the appropriate REB submission forms and checklists such as, but not limited to:

- REB application form;
- Continuing Review form;
- Amendment and/or Administrative Change form;

- Changes in Research Staff form;
 - Unanticipated Problem 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 Research Requirements: The research question and methodology is written in sufficient detail to permit evaluation of the 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 procedures;
 - Intervention allocation (if applicable);
 - Primary and secondary outcome measures;
 - Assessment of safety;
 - Sample size justification;
 - Data analysis;
 - Data monitoring;

5.2 Administrative Review Procedures

- 5.2.1 REO Personnel screens the submission for overall completeness; Incomplete submissions will not be accepted for review until the investigator has provided all necessary materials as determined by the REO Personnel. If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the REO Personnel will follow up with the Researcher and/or research coordinator to request the required information for inclusion with the submission.
- 5.2.2 A unique number is assigned to each new submission at the time of creation of a main application in the online system.
- 5.2.3 Upon receipt of a complete submission, the responsible REO Personnel identifies any outstanding items that will be required to issue approval, as applicable.
- 5.2.4 For submissions requiring Full Board review, the REO Personnel posts the submission to the available 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).
- 5.2.6 REB applications should include the hospital and institutional approvals obtained by the study team. Waivers to this requirement may be granted by the REB Chair or designee.

6.0 REFERENCES

See References