Title	REB Submission Requirements and Administrative Review
SOP Code	301.003
Effective Date	08-Oct-2019

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
Albert F Clark	*Albert F. Clark.*	06JAN2022
Jennifer Couture	*(signature)*	06JAN2022

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   SCOPE

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

3.0   RESPONSIBILITIES

All REB members and 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, checklists, number of copies, 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,
- Submission checklist,
- Continuing Review form,
- Amendment and/or Administrative Change form,
- Change in Researcher/Coordinator form,
- Changes in Research Personnel form,
- Serious Adverse Event Reporting form,
- Protocol Deviation form
- Research Completion form;

5.0.1   All project team members performing significant study-related duties, including those who have access to study data, are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external applicants. The Office of Research Ethics Compliance will accept Good Clinical Practice (GCP) and the CITI Biomedical Ethics Tutorial as equivalent ethics training modules in lieu of the CORE tutorial. The Office of Research Ethics Compliance may accept other ethics training certifications in lieu of the CORE tutorial; however, this is at the discretion of the Office of Research Ethics Compliance. Proof of equivalent ethics training must be attached to the ethics application in TRAQ;

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 interventions,
- Treatment 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   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 research coordinator 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.

6.0   REFERENCES

See References.

7.0   REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP301.001	15-Sept-2014	Original version
SOP301.002	08-Mar-2016	No revisions needed
SOP301.003	08-Oct-2019	5.1.1: Added 'Protocol Deviation form' Added 5.1.2: All project team members performing significant study-related duties, including those who have access to study data, are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external applicants. The Office of Research Ethics Compliance will accept Good Clinical Practice (GCP) and the CITI Biomedical Ethics Tutorial as equivalent ethics training modules in lieu of the CORE tutorial. The Office of Research Ethics Compliance may accept other ethics training certifications in lieu of the CORE tutorial; however, this is at the discretion of the Office of Research Ethics Compliance. Proof of equivalent ethics training must be attached to the ethics application in TRAQ;