Title	REB Submission Requirements and Administrative Review
SOP Code	301.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager		12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023

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 have adequate time to assess the proposed research and that the materials they receive allow them to adequately evaluate 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 website and the appropriate REB submission forms and checklists including, but not limited to:

- REB application form,
- Continuing Review form,
- Amendment and/or Administrative Change form,
- Change in Researcher/Coordinator form,
- Changes in Research Personnel form,
- Serious Adverse Event Reporting form,

Queen's University HSREB and GREB use two online systems: Clinical Trials Ontario (CTO) and TRAQ. CTO is used for multi-centred clinical studies.

CTO submissions have two main types of applications: provincial and centre applications. The following lists the types of provincial applications:

- **Provincial Initial Applications (PIA);**
- **Provincial Amendments (PAM);**
- **Provincial Reportable Events (PRE);**

- **Provincial Continuing Review (PCR);**
- **Provincial Study Closure (PSC);**

The following lists the types of centre applications:

- **Centre Initial Applications (CIA);**
- **Centre Amendments (CAM);**
- **Centre Reportable Events (CRE);**
- **Centre Continuing Review (CCR);**
- **Centre Study Closure (CSC);**

TRAQ submissions in HSREB include:

- **REB Quality Initiative Screening Tool;**
- **HSREB Non-Recruitment Application Form;**
- **HSREB Intermediate Application Form;**
- **HSREB Standard Application Form;**
- **HSREB Case Report Application Form;**

TRAQ submissions in GREB include:

- **REB Quality Initiative Screening Tool;**
- **GREB Standard Application Form;**
- **GREB Instructor Course-Based Research Assignment Application;**
- **GREB Secondary Use of Data Application Form;**
- **GREB Self-Study Application Form**

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

5.1.3 **Research Requirements:** The research question and methodology are written in sufficient detail to permit evaluation of the project's merit. 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 the 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/Ethical Review Procedures

5.2.1 **A unique CTO number is assigned to each event submission at the time of receipt of the application. This includes initial submissions or resubmissions.**

A unique TRAQ number is assigned to each event submission at the time of receipt of the application.

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 in the submission.

5.2.3 Upon receipt of a complete submission, the responsible REB Office Personnel **performs a preliminary ethical review of the research ethics application, attachments,** and participant-facing documents. The REB Office Personnel identifies any outstanding items required to issue approval, as applicable.

If corrections/edits/modifications or clarifications are required within any participant facing documents, this will be communicated to researcher/applicant with the use 'tracked changes' within the word document itself, utilizing the comment feature. Researchers will be required to make changes in the tracked version that is sent back (retaining the REB's comments and showing the researchers edits). The researcher will submit both a 'clean' and 'tracked changed' version back to the REB for review. The documents will be found in the 'attachments' tab of the TRAQ program and in the 'documents' tab in CTO.

Upon receipt of a completed submission, the responsible REB Office Personnel may determine that the study lacks previously requested information or is not present in the research ethics application form. The researcher may be asked to submit a new application or an

amendment to provide the necessary information and may be asked to close the current ethics application.

If the new application has been requested at the time of renewal, the current study will be renewed conditionally for a period of 30 days until receipt of the new application. Once the new application has been received, the conditional renewal will be lifted, and the study will be closed under the older REB number.

If the new application has not been received within the period of 30 days, the study will be closed.

If a research ethics application has been submitted as an umbrella study and was approved in the past, the present REB may choose not to approve this study as the amendments that continue to be submitted under the umbrella research study may have deviated from the original question. The researcher may be asked to close this application and submit a new application to the REB.

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 **application and documents for a proportionate review.**

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	No revisions needed
SOP301.004	15-May-2023	No revisions needed

SOP301.004	01-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text