

TITLE	301: HREB Submission Requirements and Administrative Review
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

This standard operating procedure (SOP) describes the Human Research Ethics Board (HREB) 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 DEFINITIONS

See Glossary of Terms.

3.0 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 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 HREB approval.

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

3.1 Submission Requirements

- 3.1.1 The required documents, checklists, number of copies, format and submission procedures are outlined on the HREB's website and on the

appropriate HREB submission forms and checklists such as, but not limited to:

- HREB 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,
- Research Completion form;

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

3.1.3 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.

3.2 Administrative Review Procedures

3.2.1 A unique number is assigned to each submission at the time of the receipt of the application. HREB Office Personnel screens the submission for overall completeness;

3.2.2 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the HREB Office Personnel will follow up with the Researcher and/or research coordinator to request the required information for inclusion with the submission;

3.2.3 Upon receipt of a complete submission, the responsible HREB Office Personnel identifies any outstanding items that will be required to issue approval, as applicable;

- 3.2.4 For submissions requiring Full Board review, the HREB 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;
- 3.2.5 For submissions reviewed via delegated review procedures, the HREB Chair or designee assigns a reviewer(s) and sends the research. Assigned reviewers receive submissions for review at the start of the week following the HREB Office’s acceptance of the submission for review.

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 301	November 14, 2019	Original version