SOP Title	Submission Requirements and Administrative Review
Number.Version	N301.003
Effective Date	03/03/2025

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance	Erika Basile	Mar 3, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board	Isha DeCoito	Mar 3, 2025

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the Non-Medical Research Ethics Board (NMREB) submission requirements, and the administrative review procedures conducted by the Office of Human Research Ethics (OHRE). This SOP applies to all submissions including but not limited to: new research projects for initial review, amendments or modifications to approved research and any new information.

2. GENERAL POLICY STATEMENT

NMREB members must rely on the documentation provided by the principal investigator for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and make the required determinations.

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

3. RESPONSIBILITY

This SOP applies to all NMREB members including the Chair and Vice-Chair(s) and to all OHRE staff.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

The OHRE is responsible for maintaining the submission requirements and for making such information available to investigators. The instructions to investigators regarding submission requirements, including deadlines and meeting dates, are available on the OHRE webpages or by contacting the OHRE.

5.1. Submission Requirements

5.1.1. The required documents, checklists, format and submission procedures are outlined on the OHRE webpages including but not limited to:

- Letter of Information/Consent (LOI/C) Guidance Document
- Amendment Form
- Continuing Ethics Review (CER) Form
- Updated Approvals

- Request for Acknowledgement (Reportable Event Form)
- Study Closure Form

5.2. **Administrative Review Procedures**

5.2.1. All applications can be viewed in the online system by the OHRE staff as soon as they are submitted by the Investigator or designee;

5.2.2. The unique system-generated number is assigned automatically to each submission at the time the application is created;

5.2.3. Upon receipt of the submission in the online WREM system, the responsible OHRE Administrative Staff conducts a preliminary review to ensure completeness of the application, including validation of the appropriate attachments to ensure that the review type is correct and eligibility of the PI;

5.2.4. If the submission is incomplete (e.g., documents are missing or incorrect documents were uploaded), the triage EO may route it back to the Investigator/study staff within the online system to make the necessary changes and to resubmit the revisions, time permitting;

5.2.5. Upon receipt of a complete submission, the triage EO assesses the submission to determine the level of review needed, and the submission is then assigned to an EO and, appropriate reviewer(s) for either Full Board or delegated review;

5.2.6. For submissions requiring Full Board review, the submissions are posted to the agenda of the next Full Board meeting and an EO and primary reviewer are assigned once the agenda is completed;

5.2.7. For submissions requiring Delegated review, the delegated reviewer may delegate the approval decision to the EO pending adequate responses to the recommendations.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) Chapter 6;
6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.108,46.115;
6.3. OHRP Guidance on Written IRB Procedures.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N301.001	Original	12/07/2015
N301.002	Updates to NMREB Chair and online submission system	05/11/2018
N301.003	Update to NMREB Chair & Administrative Corrections	03/03/2025