SOP Title	Submission Requirements and Administrative Review
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board		05/11/2016

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the Health Sciences Research Ethics Board (HSREB) 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

HSREB 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 REB is supported by administrative procedures that assure that HSREB 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 HSREB approval.

3. RESPONSIBILITY

This SOP applies to the all HSREB 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, number of copies, 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 (FYI Form)
- End of Study 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. The review type (Delegated, Full Board review) is initially done by the Investigator by filling out the appropriate online application form;

5.2.4. Once the application has been created and submitted through the online system the OHRE Administrative Staff will inform the responsible Ethics Officer (EO) that a new submission has been submitted;

5.2.5. Upon receipt of the submission, the responsible EO conducts a preliminary review to ensure completeness of the application, including validation of the appropriate attachments and to ensure that the review type is correct;

5.2.6. If the submission is incomplete (e.g., documents are missing or incorrect documents were uploaded), the 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;

5.2.7. Upon receipt of a complete submission, the submission is then assigned to appropriate reviewer(s) for either Full Board or delegated review;

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

5.2.9. For submissions requiring Delegated review, the EO routes the submission in the online system to the assigned reviewers (i.e., to the HSREB Chair or Vice-Chair(s), EO and to other reviewers as directed by the HSREB Chair, vice Chair(s) or designee).

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Chapter 6;

6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;

6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.108,46.115;

6.4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108; 21 CFR 312, 812;

6.5. OHRP Guidance on Written IRB Procedures;

6.6. FDA Information Sheets.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
301.001	Original	01/20/2014
301.002	Administrative changes for clarity	05/22/2014
301.003	Minor Administrative Changes	05/11/2016