Standard Operating Procedure: Development and Maintenance

The Sunnybrook REO web page version of this document is considered the most current. Please ensure that you have reviewed all linked documents and other referenced material within this SOP.

1.0 PURPOSE
The purpose of this standard operating procedure (SOP) is to describe the processes necessary to establish and maintain written SOPs to facilitate compliance with the principles, guidelines and regulations applicable to the ethical review and oversight of research involving human participants or human materials.

2.0 POLICY STATEMENT
Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants or human materials. SOPs describe the processes followed and documented to assure that the rights and welfare of the human participants of such research are overseen and protected in a uniform manner.

3.0 DEFINITIONS
See Glossary of Terms

4.0 RESPONSIBILITY
This SOP applies to REB members, REO staff, and REB Policy & Procedure Working Group members (as applicable). The Manager is responsible for coordinating the development, review and revision of the SOPs. The Director and Chair of the REB are responsible for granting final SOP approval.

5.0 PROCEDURES
5.1 Development, Review, Revision and Approval of SOPs
5.1.1 The Manager will review the SOPs every two years. Applicable SOPs will be reviewed earlier if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOPs;
5.1.2 Standard Operating Procedure(s) may be revised due to: changes to applicable regulations or guidance documents; new policies determined by the Director or REB Chair; or changes to REB or REO administrative practices;
5.1.3 The Manager will make the necessary modifications to existing SOPs, or draft new SOP(s). Standard Operating Procedure(s) are controlled documents and new drafts will be indicated by the addition of DRAFT revision date;
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5.1.4 The revised draft SOP(s) will be circulated to REO staff, REB Chair/Vice-Chair, Director, as well as REB members (as applicable) for review;

5.1.5 Each SOP will be identified by a number. The number format follows the sequence: The letters REB, followed by the letters SOP, followed by the section number, followed by the SOP number and version number (i.e. REB-SOP-II-01.001). For revisions to previous SOPs, the version number will be revised to the next consecutive number (e.g. 01.001 becomes 01.002). This new version supersedes any previous versions;

5.1.6 Once the final draft is approved, the draft version date will be removed and the date of the approved revision will be entered. For an original SOP, the original issue date will be recorded in the header. For subsequent SOPs, the revision date will be recorded in the header.

5.1.7 A revision summary will be completed for each SOP. This revision summary will also serve as the approval form for any SOP. Standard Operating Procedure(s) are approved by the Director and REB Chair.

5.1.8 For policies, the Institutional Policy Approval Form will be used to track approval for both original and revised policies. Policies, as designated in the title, require approval from the Medical Advisory Committee (MAC);

5.1.9 Standard Operating Procedure(s) and Policies will be archived as per Health Canada requirements.

5.2 Distribution and Communication

5.2.1 The Director or designee is responsible for ensuring new or revised SOPs, policies and associated guidance documents will be communicated and disseminated to individuals identified in the responsibilities section of each SOP;

5.2.2 REB members will be provided with access to all applicable SOPs and policies;

5.2.3 REO staff must review all new and revised SOPs and policies. The Director or designee shall maintain documentation of SOP training in the SOP training record.

5.3 Forms

5.3.1 Forms, including checklists and worksheets, are used to facilitate compliance with SOPs. Forms are either controlled or non-controlled;

5.3.2 Controlled forms are documents that require formal change control through use of version dates and are part of the permanent record of REB operations and processes;

5.3.3 Non-controlled forms are management tools that are not part of the permanent record of REB operations and processes. Non-controlled forms should also contain version dates.

6.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
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2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.

List the applicable regulations and guidelines the SOP is governed by.