

SOP Title:	Standard Operation Procedure Development and Maintenance		
SOP #:	I.01.001	Original Issue Date:	February 23, 2015
Category:	General Administration	Reviewed/Effective Date:	October 1, 2019
Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for establishing and maintaining 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 the REB members and REO Personnel. The REO Manager is responsible for coordinating the development, review and revision of the SOPs. The REB Chair is 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 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;

- 5.1.4 The revised draft SOP(s) will be circulated to REO staff, REB Chair/Vice-Chair, 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 section number, followed by the SOP number and version number (i.e. 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 REB Chair.
- 5.1.8 Standard Operating Procedure(s) and Policies will be archived as per Health Canada requirements.

5.2 Distribution and Communication

- 5.2.1 The REO Manager 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 REO Manager 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

See References