



Standard Operating Procedures
001-01

1. Purpose

The objective of this standard operating procedure (SOP) is to guide the SOP development process, define commonly used terms and acronyms, standardize quality controls for Methods Centre (MC) operations and projects and provide clear direction to MC staff regarding the execution of their responsibilities.

2. Responsibilities

Director of Clinical Evaluation Research Unit (CERU): Review and approval of SOPs.

SOP Working Group: Facilitate the development and management of SOPs for the MC.

Methods Centre Staff: Review and reference SOPs to properly execute roles and responsibilities.

3. Procedures

3.1 The following is a glossary of commonly referred to terms used throughout method centre SOPs:

- 3.1.1 Clinical Evaluation Research Unit (CERU): the methods centre for the conduct of critical care related research located at Kingston General Hospital.
- 3.1.2 Good Clinical Practices (GCP): generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of research study participants.
- 3.1.3 Investigational Product: refers to a drug or device, as defined by governing regulations, to be tested in a research study.
- 3.1.4 Methods Centre (MC): a group of clinical experts and operational staff with an expertise in:
 - 3.1.4.1 study design, including randomized controlled trials, surveys, clinical practice guidelines and quality of life measures
 - 3.1.4.2 operational planning and implementation
 - 3.1.4.3 data management
 - 3.1.4.4 statistical analysis
- 3.1.5 Project Leader (PL): the individual delegated the authority by the Sponsor to manage all aspects of the study, including but not limited to: pre-study activities, implementation activities and closeout activities. Additional responsibilities may be delegated by the Sponsor.
- 3.1.6 Qualified Investigator (QI): the individual located at the research site responsible to the Sponsor for the conduct of the study at the research site, who is entitled to provide health care under the laws of the country, province/state where the research site is located. Is a physician and a member in good standing of a professional medical association.
- 3.1.7 Regulatory Documents: Documents, in any form, which individually or collectively permit the evaluation of a research study and the quality of the data.
- 3.1.8 Research Site: the location(s) where the study-related activities are actually conducted. Research site includes the local institution, qualified investigator, and research team.
- 3.1.9 Research Team: Refers to an individual or group of individuals involved with the initiation, management and conduct of study-related duties and functions.
- 3.1.10 Standard Operating Procedures (SOP): a written instruction to achieve uniformity of the performance of a specific function.
- 3.1.11 SOP Working Group: the group of individuals located at the methods centre involved with the development and maintenance of SOPs.
- 3.1.12 Sponsor: also referred to as Principal Investigator (PI), is an individual, corporate body, institution or organization that conducts a study.



Standard Operating Procedures
001-01

- 3.1.13 Study: refers to an investigation involving human participants that is intended to discover new information for the further advancement of knowledge concerning the prevention, diagnosis, treatment and management of medical conditions and their outcomes. This includes randomized-controlled trials, observational studies, surveys or other types of projects.
- 3.1.14 Work Instruction (WI): an instructional document which outlines tasks and functions already established in SOPs to a greater degree of specificity for individual projects or studies.

3.2 The following sections outline the procedures involved in the development of SOPs:

- 3.2.1 All SOPs will be written using the MC SOP template, which includes the following:
 - 3.2.1.1 Brief, informative title
 - 3.2.1.2 SOP Number
 - 3.2.1.3 Version Date
 - 3.2.1.4 Author
 - 3.2.1.5 Approval Signature
 - 3.2.1.6 Revision History
 - 3.2.1.7 Purpose
 - 3.2.1.8 Responsibilities
 - 3.2.1.9 Procedures
 - 3.2.1.10 Appendix, if applicable
 - 3.2.1.11 References
- 3.2.2 The MC may identify or be informed of a procedure that requires development.
- 3.2.3 The SOP Working Group will be informed of the intent to develop the procedure, and when necessary, be provided with information regarding stakeholders to provide input into procedure development.
- 3.2.4 The SOP Working Group will ensure that a similar procedure does not exist.
- 3.2.5 The SOP Working Group will develop a draft procedure using the SOP template.
- 3.2.6 The draft SOP will undergo a 3-step review process:
 - 3.2.6.1 Review by stakeholders and interested parties, if applicable
 - 3.2.6.2 Review by the SOP Working Group
 - 3.2.6.3 Review and approval by the Director of CERU
- 3.2.7 When the draft procedure has been approved by the Director of CERU, the SOP will be signed by the Director of CERU.
- 3.2.8 The SOP effective date will be the approval date.
- 3.2.9 Once the draft procedure has undergone the complete review process it will be issued a SOP number (see section 3.4).
- 3.2.10 The newly approved and numbered SOP will be filed either in hard copy or electronically.
- 3.2.11 All appropriate MC staff will be trained on newly approved SOPs (see SOP 207).
- 3.2.12 The SOP development process will be tracked on the SOP Development Worksheet (Appendix 4.1).



Standard Operating Procedures 001-01

3.3 The following sections outline the procedures involved in revising existing SOPs:

- 3.3.1 All SOPs will undergo a review. Reasons for review include, but are not limited to:
 - 3.3.1.1 The SOP does not adequately describe how a procedure is being performed.
 - 3.3.1.2 The SOP is found to be non-compliant with regulatory guidelines and governing regulations.
 - 3.3.1.3 Multiple SOP deviations have been reported.
- 3.3.2 Revision begins with the SOP Working Group sending a communication to all MC staff indicating that the SOP is undergoing a review and possible revision. Staff will be instructed to forward any commentary to a designated individual of the SOP Working Group.
- 3.3.3 Steps 3.2.6 to 3.2.11 will be followed.
- 3.3.4 All changes from a previously approved SOP should be documented on the SOP Revisions Log (Appendix 4.2). The SOP Revisions Log is an audit trail of all changes made to previously approved SOPs.
- 3.3.5 When the SOP has undergone the complete revision process the SOP number will be updated accordingly (see section 3.4).
- 3.3.6 The SOP revision process will be tracked on the SOP Development Worksheet (Appendix 4.1).

3.4 The following procedures should be followed when numbering SOPs:

- 3.4.1 Each SOP will be issued a unique number XXX-YY.
 - 3.4.1.1 "XXX" refers to the sequential number of a SOP within a series. The series of SOPs and corresponding numbers are as follows:
 - 3.4.1.1.1 General Topics (000-099)
 - 3.4.1.1.2 Administration (100-199)
 - 3.4.1.1.3 Study Setup (200-299)
 - 3.4.1.1.4 Study Implementation and Conduct (300-399)
 - 3.4.1.1.5 Data Management (400-499)
 - 3.4.1.1.6 Study Closeout (500-599)
 - 3.4.1.1.7 Quality Assurance (600-699)
 - 3.4.1.2 "YY" refers to the revision status of the SOP. The revision status of the SOP is indicated as follows:
 - 3.4.1.2.1 First effective version of SOP "00"
 - 3.4.1.2.2 Second effective version of SOP (i.e. first revision) "01"
 - 3.4.1.2.3 Etc...

4. Appendix

- 4.1 SOP Development Worksheet
- 4.2 SOP Revision Log



Standard Operating Procedures
001-01

5. References

5.1 ICH GCP section 5.1: Quality Assurance and Quality Control

5.2 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.010(c).



SOP Development Worksheet

SOP #	
SOP Title	

Initial SOP Development

Written by: _____ Date: _____

Reviewed by: _____ Date: _____

Director Review Date: _____ Approval: YES NO

Effective Date: _____

SOP Revision

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____

Revision #: _____ Reviewed By: _____ Date: _____



Standard Operating Procedures Revisions Log

SOP #	
SOP Title	
Revision #	

Revisions:

Type of Revision	Page	Section	Description of Change

Revised By: _____
Janet Overvelde, Project Leader

_____ Date