STANDARD OPERATING PROCEDURE ON SOPs: PREPARING, MAINTAINING AND TRAINING

SOP Number: GCP GA 100.03	
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Superseded Version Number & Date (if applicable): 2nd version; 17 June 2010	**Review Date:** 30 Apr 2015

Revision Chronology:		
Version Number	**Version Date**	**Reason for Change**
100.01	**04 August 2005**	**Initial Version**
100.02	**17 June 2010**	**Review and Update; Compliance with Lawson SOPs**
100.03	**25 Apr 2013**	**Review**

	Printed Name	Signature	Date (dd/mmm/yyyy)
Written By:	Sandra Blamires	_____	____/_____/_____
Reviewed By:	Dan Buchanan	_____	____/_____/_____
Approved By:	Grace Parraga	_____	____/_____/_____

1. INTRODUCTION & PURPOSE

Standard operating procedures (SOPs) describe the processes that must be followed when conducting clinical research with human participants. These SOPs are based on Canadian and international guidelines and regulations governing clinical research. The purpose of these documents is to provide performance guidelines, promote consistency, ensure compliance with applicable regulations and guidelines, and to facilitate training of new personnel.

2. SCOPE

This SOP describes the processes for the development, review, approval, and maintenance of the written standard operating procedures, as well as the processes for training personnel on these procedures and documentation of training.

3. APPLICABLE REGULATIONS AND GUIDELINES

Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials
FDA Code of Federal Regulations, Title 21
International Conference on Harmonisation; Good Clinical Practice: Consolidated Guidelines
Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans

4. REFERENCES TO OTHER APPLICABLE SOPs

All clinical research SOPs must conform to this SOP

5. ATTACHMENTS

A. Training Compliance Form
B. SOP Index
C. SOP Template
D. Hard Copy SOP Distribution Record

6. RESPONSIBILITY

This SOP applies to all clinical personnel involved in writing, revising, reviewing, approving, and maintaining SOPs.

This includes (but is not limited to) the following:

- Principal, Qualified and Co- Investigators
- Facility Managers
- Clinical Research Coordinator
- Collaborators
- Research Assistants, Associates and Technicians
- Students and Post-Doctoral Fellows

7. DEFINITIONS

The following definitions apply to this SOP:

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

8. PROCESS OVERVIEW

A. Procedure for preparing new SOPs or revising previously issued SOPs
B. Procedure for reviewing and approving SOPs
C. Procedure for maintaining SOPs
D. Procedure for providing training on new and revised SOPs

9. PROCEDURES

A. Procedure for Preparing New SOPs or Revising Previously Issued SOPs

1. Based on either the findings from a scheduled SOP review or changes to regulations, guidelines, research practice, or institutional policies, any clinical research personnel can identify the need for new/revised SOPs.
2. A member of the research team who is qualified by experience, skills and training will draft a new or revised SOP.
    a. New SOPs will be given the next consecutive number available in the appropriate category. The version number of a new SOP is .01
    b. For revised SOPs, the version number is increased consecutively
3. The author of the SOP should evaluate the need for new or revised forms associated with the SOP that would assist in compliance with the SOP.

4. The SOP author will write the SOP following the standard format (Attachment C), indicating in the footer that it is a draft. The version number will be revised to the next consecutive number.
5. The SOP index will be updated as necessary.

B. Procedure for Reviewing and Approving SOPs

1. Each new/revised SOP will be reviewed by at least one other member of the clinical research team who is familiar with the procedures and regulations.
2. The SOP author will incorporate accepted comments from the reviewer(s).
3. The peer reviewed SOP will be reviewed by the principal investigator (PI) for accuracy, completeness and compliance with regulations, guidelines and standard practice.
4. The PI will return the SOP to the author, identifying any required revisions or indicating that the SOP is complete.
5. The author will incorporate required revisions as identified by the PI.
6. Repeat steps 3 to 5 until the SOP is deemed acceptable by the principal investigator, at which time the author will remove the word draft from the footer and add the effective date and review date to the front page.
7. The principal investigator will sign the front page indicating their approval for the SOP to be implemented on the effective date.

C. Procedure for Maintaining SOPs

1. SOPs will be reviewed within two years of the effective date, or sooner if there are significant changes to regulations, guidelines, research practice or institutional policies.
2. Even if no changes are required, the version number, version date and effective date should be amended to indicate that the review has occurred.
3. Once a new/revised SOP is approved, the SOP index must be updated, the SOP must be filed in the SOP manual, and, if applicable, the previous version must be archived in case of audit.
4. The original signed version of all current SOPs, as well as the signed copy of all archived SOPs will be stored in the office of the research coordinator. All original, approved, hard copy SOPs should be retained for no less than 25 years from the effective date.
5. If hard copies of approved versions are distributed, it must be recorded in the SOP distribution record (Attachment D). This record will be used to collect old versions of SOPs when a new version is approved. The distribution record will be kept with the current SOP manual in the research coordinator's office.
6. An electronic copy of the current SOPs will be available to all site personnel in read-only format. Printing of SOPs is discouraged, and printed SOPs should be used as a reference only.

D. Procedure for Providing Training on New and Revised SOPs

1. The PI must ensure that all personnel receive training on new or revised SOPs within one month of the effective date of the SOP.
2. All personnel must document training using the training compliance form (Attachment A). These forms will be stored in the SOP training binder in the research coordinator's office.
3. The PI must ensure that all new personnel receive training on SOPs before undertaking any responsibilities for which the SOPs apply.