



1. Purpose

The purpose of this SOP is to provide a general overview of responsibilities and activities associated with day-to-day operations for Clinical Evaluation Research Unit (CERU) research studies.

2. Responsibilities

Principal Investigator: The Principal Investigator (PI), sometimes referred to as Sponsor, is responsible for oversight of the activities outlined in this procedure.

Methods Centre: The Methods Centre (MC), under the direction of the PI, is responsible for adhering to ICH Good Clinical Practices and governing regulations concerning the conduct of research studies.

3. Procedures

3.1 A Principal Investigator/Sponsor is defined as *“an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.”* ICH GCP 1.53.

3.2 As per the Canadian Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects, *“every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that:*

- 3.2.1 *The clinical trial is scientifically sound and clearly described in a protocol;*
- 3.2.2 *The clinical trial is conducted, and the drug is used in accordance with the protocol and this Division;*
- 3.2.3 *Systems and procedures that assure the quality of every aspect of the clinical trial are implemented;*
- 3.2.4 *For each clinical trial site, the approval of a research ethics board (REB) is obtained before the clinical trial begins at the site;*
- 3.2.5 *At each clinical trial site, there is no more than one qualified investigator;*
- 3.2.6 *At each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the qualified investigator;*
- 3.2.7 *Each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;*
- 3.2.8 *Written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of*
 - 3.2.8.1 *The risks and anticipated benefits of his or her health arising from participation in the clinical trial, and*
 - 3.2.8.2 *All other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;*
- 3.2.9 *The requirements respecting information and records are met; and*
- 3.2.10 *The drug is manufactured, handled and stored in accordance with the applicable good manufacturing practices.*

3.3 When appropriate, the PI may delegate the above mentioned duties and responsibilities to MC staff. Refer to SOP 201: Delegation of Authority.



Study Operations 202-00

Standard Operating Procedures (SOPs)

- 3.4 The MC follows SOPs that meet or exceed ICH GCP guidelines, and government regulations to ensure standardization of activities across the organization. Refer to SOP 001: Standard Operating Procedures.
- 3.5 The MC provides participating research sites with study specific procedures and work instructions to facilitate compliance and consistency in the execution of study related activities. Refer to SOP 002: Work Instructions.

Training

- 3.6 The PI and delegated MC staff should have appropriate training in clinical research procedures and/or regulations prior to participating in a research study activities. Refer to SOP 207: Training of Research Team.
- 3.7 Before each study begins, a training session should be held to educate and inform research sites involved in the study of their roles and responsibilities and the specific requirements of the study.

Research Ethics Board (REB)

- 3.8 A study must be reviewed and approved by a duly constituted REB at each research site prior to the initiation of any study activities. Refer to SOP 203: Research Ethics Board Submission Activities.

Documentation

- 3.9 Data reported in case report forms must be derived from source documents and records. The research site will maintain these documents and records for a period of 25 years.
- 3.10 All regulatory and study-related essential documentation should be updated on an ongoing basis throughout the study period and must be maintained for a period of 25 years.
- 3.11 All qualified investigators at the research sites should support local institutional policies regarding confidentiality of patient information.
- 3.12 All qualified investigators at the research site should support MC requirements for confidentiality of information related to research studies.
- 3.13 The MC will document all operational aspects of the study on an ongoing basis (e.g. tracking logs, monitoring reports, research site communications).

4. References

- 4.1 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects
- 4.2 ICH GCP Section 5.0: Sponsor