





## 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 operations and projects at the Clinical Evaluation Research Unit (CERU) and provide clear direction to CERU staff regarding the execution of their responsibilities.

**DISCLOSURE:** Kingston General Hospital joined the N<sub>2</sub> organization as a member. In accordance with KGH Administrative Policy 11-152: Standard Operating Procedures for Research, research groups located within the Institution are advised to use the N<sub>2</sub> SOP's, Tools (sample source documents), and any of the training sessions offered through the N<sub>2</sub> organization.

The Director of CERU, and delegates, has ensured that the content of CERU SOPs is consistent with that provided in the N<sub>2</sub> organization procedures. However in addition, CERU SOPs are specific to conducting research in critical care and other specialized clinical settings.

## 2. Responsibilities

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

**SOP Administrator:** Leads the SOP development and management processes as well as the SOP Working Group at CERU.

**SOP Working Group:** Facilitate the development and management of SOPs for CERU. Ensure SOPs are in compliance with the applicable GCP guidelines, and related documents.

**CERU 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 CERU SOPs:

3.1.1 Clinical Evaluation Research Unit (CERU): the methods centre which conducts research in critical care and other specialized clinical settings. CERU is located at Kingston General Hospital.

CERU comprises a group of clinical experts and operational staff with an expertise in:

- 3.1.1.1 Study design, including randomized controlled trials, surveys, clinical practice guidelines and quality of life measures
- 3.1.1.2 Operational planning and implementation
- 3.1.1.3 Data management



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3.1.1.4 Statistical analysis

- 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 (IP): refers to a drug or device, as defined by governing regulations, to be tested in a research study.
- 3.1.4 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.
- 3.1.5 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.
- 3.1.6 Regulatory Documents: Documents, in any form, which individually or collectively permit the evaluation of a research study and the quality of the data.
- 3.1.7 Research Site: the location(s) where the study-related activities are actually conducted. Research site includes the local institution, qualified investigator, and research team.
- 3.1.8 Research Team: Refers to an individual or group of individuals involved with the initiation, management and conduct of study-related duties and functions.
- 3.1.9 Standard Operating Procedures (SOP): a written instruction to achieve uniformity of the performance of a specific function.
- 3.1.10 SOP Administrator: Individual delegated the responsibility by the Director of CERU to lead the SOP development and management processes at CERU. The SOP Administrator leads the SOP Working Group.
- 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.
- 3.1.13 Study or Trial: 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:



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3.2.1 All SOPs will be written using the CERU 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 CERU may identify or be informed of a procedure that requires development.

3.2.3 The SOP Administrator will be notified and will ensure that a similar procedure does not exist. The SOP Administrator will begin developing the procedure, and when necessary, be provided with information regarding stakeholders to provide input into procedure development.

3.2.4 The SOP Administrator will develop a draft procedure using the CERU SOP template.

3.2.5 The draft SOP will undergo a 3-step review process:

- 3.2.5.1 Review by stakeholders and interested parties, if applicable
- 3.2.5.2 Review by the SOP Working Group or individual members. See Appendix 4.1, SOP Working Group Membership.
- 3.2.5.3 Review and approval by the Director of CERU

3.2.6 When the draft procedure has been approved by the Director of CERU, the SOP will be signed by the Director of CERU.

3.2.7 The SOP effective date will be the approval date.

3.2.8 Once the draft procedure has undergone the complete review process it will be issued a SOP number (see section 3.4).

3.2.9 The newly approved and numbered SOP will be filed in a secure location both in hard copy and electronically.

- 3.2.9.1 Electronic versions are stored on a backed up institutional network.
- 3.2.9.2 Electronic versions can be accessed by CERU staff on the Q drive/Standard Operating Procedures/SOP

3.2.10 All appropriate CERU staff will be informed of approved SOPs (see SOP 207). Training will consist of either group sessions or self-review (refer to SOP 207: Methods Centre Staff Qualifications and Training).



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- 3.2.11 The SOP development process will be tracked on the SOP Development Worksheet (Appendix 4.2).
- 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:
    - 3.3.2 Regularly scheduled review every 2 years from the effective date.
    - 3.3.3 The SOP does not adequately describe how a procedure is being performed.
    - 3.3.4 The SOP is found to be non-compliant with regulatory guidelines and governing regulations.
    - 3.3.5 Multiple SOP deviations have been reported.
    - 3.3.6 Revision begins with the SOP Administrator sending a communication to all CERU staff indicating that the SOP is undergoing a review and possible revision. Staff will be instructed to forward any commentary to the SOP Administrator.
    - 3.3.7 Steps 3.2.6 to 3.2.11 will be followed.
    - 3.3.8 All changes from a previously approved SOP should be documented on the SOP Revisions Log (Appendix 4.3). The SOP Revisions Log is an audit trail of all changes made to previously approved SOPs.
    - 3.3.9 When the SOP has undergone the complete revision process the SOP number will be updated accordingly (see section 3.4).
    - 3.3.10 The SOP revision process will be tracked on the SOP Development Worksheet (Appendix 4.2).
- 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...



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3.5 SOPs will be retained for a period of 25 years following the effective date.

## **4. Appendix**

4.1 SOP Working Group Membership

4.2 SOP Development Worksheet

4.3 SOP Revision Log

## **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).

5.3 Kingston General Hospital Administrative Policy 11-152: Standard Operating Procedures for Research

5.4 Network of Networks Standard Operating Procedures for Clinical Research (N<sub>2</sub> organization).



## SOP Development Worksheet

SOP #	
SOP Title	

### Initial SOP Development

Written by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Director Review Date: \_\_\_\_\_ Approval:  YES  NO

Version Date: \_\_\_\_\_

### SOP Revision

Revision #: \_\_\_\_\_ Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

Revision #: \_\_\_\_\_ Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

Revision #: \_\_\_\_\_ Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

Revision #: \_\_\_\_\_ Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

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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