SOP 002_02

Title	Research Team Roles and Responsibilities
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Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the necessary organizational elements and planning of clinical studies. This SOP identifies all members of the research team, and defines their roles and responsibilities.

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site (Erie Shore Health Care), and to those clinical research personnel responsible for performing, reviewing, and/or approving the study related activities.

3.0 RESPONSIBILITIES

All institutional personnel working in clinical research involving human subjects are responsible for performing their roles, as described in this document.

The Investigator/ Qualified Investigator (QI) is responsible for ensuring that the research team under his/her supervision complies with all regulations, policies, and procedures.

4.0 DEFINITIONS

Sponsor: an individual, company, institution or organization which takes responsibility for the initiation, management, or financing of a clinical study.

Sponsor-Investigator: an individual who both initiates and conducts alone, or with others, a clinical study, and under whose immediate direction the investigational product is administered to the subject. The term does not include any person other than an individual (it does not include a corporation or an agency).

Qualified Investigator (QI) (terminology as applied to a clinical study covered by Division 5 of the Canadian Food and Drug Regulations): the person responsible to the sponsor for the conduct of the clinical study at a clinical study site, who is entitled to provide health care under the laws of the province where that clinical study site is located, and who is:

- In the case of a clinical study respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association.
- In any other case, a physician and a member in good standing of a professional medical association.

Investigator or Principal Investigator (terminology as applied to a clinical study not covered by Division 5 of the Canadian Food and Drug Regulations): A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Sub-investigator: any individual member of the clinical study team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (associate, residents, research fellows, nurses).

Clinical Research Coordinator (CRC)/ Clinical Research Personnel (CRP): a specially trained professional (nurse, health professional or other qualified clinical research team member) who manages most of the day-to-day responsibilities of a clinical trial.

5.0 PROCEDURE

5.1 Creation of a Research Team

5.1.1 Clinical research personnel must understand the responsibilities of the clinical research site, and be appropriately qualified by education, training and experience to perform their study-related task(s).

5.1.2 In preparation for a clinical study, the Qualified Investigator (QI)/Investigator or his/her delegates should:

- Appoint members of the research team who will be involved in the study (before submitting to the REB/IEC, where applicable);
- Determine, at the beginning of the study, each team member's role, and the availability of relief personnel;
- Identify team members who need training on GCP and other applicable regulations and guidelines;
- Schedule training in protocol content and application; and
- Maintain a list of appropriate qualified persons to whom he/she has delegated significant study-related duties.

5.1.3 The QI/Investigator must ensure that all persons assisting with the study are adequately informed about the protocol, investigational products and their study-related duties and functions..

5.2 Roles and Responsibilities of the Sponsor

5.2.1 The Sponsor is responsible for ensuring that:

- The clinical study is scientifically sound and clearly described in a protocol;
- The clinical study is conducted, and the research product, if applicable, is used, in accordance with the protocol;

- Systems and procedures that assure the quality of every aspects of the clinical study are implemented;
- The approval of a Research Ethics Board (REB)/Independent Ethics Committee(IEC) is obtained before the clinical study begins at the site;
- There is no more than one QI at each clinical study site;
- Medical care and medical decisions, in respect of the clinical study, are under the supervision of the QI;
- Each individual involved in the conduct of the clinical study is qualified by education, training and experience to perform his or her respective tasks;
- Written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical study, but only after that person has been informed of the risks and anticipated benefits to his or her health arising from participation in the clinical study, and all other aspects of the clinical study that are necessary for that person to make the decision to participate in the clinical study;
- The requirements respecting information and records set out in Section C.05.012 of the Health Canada, Food and Drug regulations are met (if applicable); and
- The drug/s is/are manufactured, handled and stored in accordance with the applicable good manufacturing practice (GMP) regulations of Health Canada (If applicable).

5.3 Roles and Responsibilities of the Sponsor-Investigator

5.3.1 The obligations of a Sponsor-Investigator include both those of a Sponsor (described in 5.2 above) and those of a Qualified Investigator/ Investigator (described in 5.4 below).

5.4 Roles and Responsibilities of the Qualified Investigator (QI)/Investigator

5.4.1 The QI/Investigator is responsible for the well-being of research subjects, the conduct of the study, administration of the investigational product, if applicable, team and space requirements, conformity with the requirements of the REB/IEC and GCP team training.

5.4.2 Although some of these tasks may be delegated to other qualified clinical trials staff members, the QI/Investigator assumes ultimate responsibility for the overall conduct of a clinical trial and for compliance with all applicable regulations and guidelines. The QI must document the delegation of tasks/duties (see Section 5.7 Documentation of Task Delegation).

5.4.3 The QI/Investigator must:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study, meet all the qualifications specified by the applicable regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and all other relevant documentation requested by the Sponsor/Sponsor-Investigator, the REB/IEC and the regulatory authorities;
- Be thoroughly familiar with the appropriate use of the investigational products as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the Sponsor or Sponsor/Investigator;
- Be aware of and should comply with, other applicable regulations and guidelines;
- Permit monitoring for the clinical study and auditing by the Sponsor-Sponsor-investigator, and inspection by the appropriate regulatory authorities; and
- Make all study-related medical decisions.

5.4.4 The QI/Investigator must also ensure that:

- All persons assisting with the study are adequately informed about the protocol, investigational product(s) and their study-related tasks and roles;
- Adequate medical care is provided to a subject in the case of any adverse event;
- A written and dated approval/favourable opinion from the REB/IEC for the study protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements) and any other written information to be provided to subjects has been granted before the study is begun at the site;
- The study is conducted in compliance with the protocol approved by the Sponsor or Sponsor-Investigator, the REB/IEC and, if applicable, appropriate regulatory authorities, such as Health Canada;
- Make all study-related medical decisions;
- The data reported to the Sponsor or Sponsor-Investigator in the CRFs and in all required reports are accurate, complete, and timely;
- All study documents are maintained up to date as specified in Essential Documents for the Conduct of a Clinical Study and as required by the applicable regulatory requirements;
- Necessary measures are taken to prevent accidental or premature destruction of essential study documents for a clinical study; and
- All serious adverse events are immediately reported to the Sponsor or Sponsor-Investigator and applicable regulatory authorities.

5.4.5 Responsibility for investigational product at the study site rests with the QI/Investigator/ and the institution. The QI/Investigator should ensure that the investigational product is used only in accordance with the approved protocol. Where allowed/required, the QI/Investigator or institution may/should assign some or all of the QI/Investigator's/institution's tasks for investigational product(s) storage, dispensing, and accountability at the study site to an appropriate pharmacist or another appropriate individual who is under the supervision of the QI/Investigator and/or institution.

5.4.6 The QI/Investigator or a person designated by the QI/Investigator or Institution should explain to each subject the appropriate use of the investigational product to study subjects and should verify, at regular intervals, if all subjects are following instructions appropriately;

5.4.7 For Division 5 trials only: The QI must complete and sign a Health Canada, Qualified Investigator Undertaking (QIU) Form for clinical trials conducted in Canada. There must be no more than one QI per study per site. If anInvestigational New Drug (IND) application for the investigational product has been submitted to the US, a Form FDA 1572 must also be completed. By signing these forms, the QI agrees to conduct the study in accordance with and other applicable regulations and guidelines, and acknowledges his/her responsibilities as defined by the regulatory bodies.

5.5 Roles and Responsibilities of the Clinical Research Coordinator (CRC)

5.5.1 The CRC works in collaboration with the QI/Investigator, and with a multidisciplinary research team to ensure that rigorous clinical trial standards are maintained. The CRC assesses the skills required and obtains the necessary training, for each protocol.

5.5.2 The specific roles of the CRC are described in the procedures of each SOP. However, in general the CRC (alone or with the assistance of other research team personnel):

- Works closely with the QI/Investigator to organize, plan and carry out the clinical trial in an efficient and timely manner including: preparing the REB/IEC submission; providing subjects with all pertinent information regarding the clinical study; coordinating subject appointments and monitoring visits; executing clinical study-related procedures with the authorization of the QI/Investigator; and completing case report forms (CRFs), ensuring that CRF entries are consistent with source documents;
- Liaises with hospital departments (laboratory, pharmacy, radiology, etc.) and REB/IEC;
- Adheres to the , other guidelines, regulations, and standard operating procedures, remaining current on guidelines, regulations and SOPs by attending or obtaining regular refresher training; and
- Acts as a subject advocate.

5.6 Roles and Responsibilities of Other Parties

5.6.1 Other parties may be involved in generating clinical study data (e.g., research and testing laboratories, pharmacy etc.). At the request of the investigator, these parties must be added to the Tasks Delegation or Assignment of Responsibilities form.

5.6.2 During a clinical study, an active role may be played by the pharmacist (if required by the protocol). Study medication can be prepared, distributed, and stored by the pharmacy. Moreover, delivery, dispensing to subjects, recording and, if necessary, disposal of the study medication, can all be managed by the pharmacist.

5.7 Documentation of Task Delegation

5.7.1 The QI/Investigator must maintain a list of appropriately qualified persons to whom he/she has delegated significant study-related tasks. Such a list must include the following information:

- Names of team members in printed in block letters or typed,
- Sample complete signature and initials of each team member (dated),
- Tasks specification or roles delegated, and
- Start and end dates of delegation.

5.7.2 The signatures and initials of all persons authorized to make entries and/or corrections on CRFs, must be recorded, to permit an evaluation of the conduct of the clinical study and the quality of the data.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

Part 11, Electronic Records; Electronic Signatures, (21CFR11).

- Part 50, Protection of Human Subjects, (21CFR50).
- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).