Vancouver CoastalHealth Research Institute

STANDARD OPERATING PROCEDURE

Research Team Roles and Responsibilities

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Site Approval

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Document History

Version	Summary of Changes Made	Effective Date
1	Original document.	09-JUL-2010
2	This version has undergone extensive revision for administrative, educational, regulatory, and clinical changes by individual content experts and the VCHRI SOP Committee. This document has also had substantial formatting, grammatical and glossary updates. It has been classed as a rewritten document.	10-JAN-2016
3	This version has undergone revision for administrative, education, regulatory and clinical changes by individual content experts and VCHRI SOP Committee. There have been changes made to 6.1.3, 6.4.3.3, 6.4.3.4, 6.4.3.5, 6.4.3.6, 6.4.4.3, 6.4.4.8, 6.4.4.10, 6.4.7, 6.5.2.1, 6.5.2.4 (omitted), 6.6.1, 6.6.3, 6.7.2.1, 6.7.2.5. References and definitions have been updated.	01-Jun-2021

1. **PURPOSE**

1.1. This Standard Operating Procedure (SOP) describes the roles and responsibilities of the research team. It also describes the documentation related to delegation of Clinical Trial/Study responsibilities to the Research Team Members.

2. SCOPE

2.1. This SOP applies to all clinical Research Team Members involved in the conduct of a Clinical Trial/Study at the Institution.

3. RESPONSIBILITIES

3.1. All Research Team Members involved in the conduct of a Clinical Trial/Study are responsible for performing their roles, as described in this document.

3.2. The Principal Investigator has ongoing involvement in the Clinical Trial/Study and is responsible for the overall conduct and oversight of the Clinical Trial/Study at the site level, and for ensuring the Research Team Members under his/her supervision comply with applicable regulations, policies and procedures.

3.3. Any delegation or transfer of study related tasks or activities from the Principal Investigator to a person or an organization (commercial, academic or other), to perform one or more of a Principal Investigator's or Sponsor-Investigator's or Clinical Trial/Study related duties and functions will be documented in a contract and/or log. Study related responsibilities include:

3.3.1. Ensuring the safety and well-being of study Participants;
3.3.2. Providing adequate resources for the conduct of the Clinical Trial/Study at the Study Site,
3.3.3. Communicating with the Research Ethics Board regarding the Protocol and any Protocol amendments;
3.3.4. Performing Clinical Trial/Study procedures as per the Protocol;
3.3.5. Following randomization procedures (if applicable);
3.3.6. Obtaining Informed Consent from Participants;
3.3.7. Recording and reporting data from the Clinical Trial/Study site, preparing and submitting progress reports, reporting safety events and completing final Clinical Trial/Study reports;
3.3.8. Active and ongoing communication with Clinical Trial/Study Participants throughout the duration of the Clinical Trial/Study;
3.3.9. Providing adequate supervision of any third parties (e.g., vendors) involved in or delegated tasks or activities for the Clinical Trial/Study.

4. RELATED SOPS/DOCUMENTS

VCHRI Tool - Orientation Checklist: Skills Assessment
VCHRI Tool - Task Delegation Log

5. DEFINITIONS

5.1. **Sponsor:** An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a Clinical Trial/Study.

5.2. **Sponsor-Investigator:** An individual who both initiates and conducts alone, or with others, a Clinical Trial/Study, and under whose immediate direction an Investigational Product is administered to, dispensed to, or used by a Participant. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a Sponsor-Investigator include both those of a Sponsor and those of an Investigator.

5.3. **Qualified Investigator:** Health Canada terminology as applied to a Clinical Trial/Study covered by Division 5 of the Canadian Food and Drug Regulations. The person responsible to the Sponsor for the conduct of the Clinical Trial/Study site, who is qualified to provide health care under the laws of the province where that Clinical Trial/Study is located, and who is:

5.3.1.1. In the case of a Clinical Trial/Study regarding 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.
5.3.1.2. In any other case, a physician and a member in good standing of a professional medical association.
5.3.1.3. There must only be one Qualified Investigator per Clinical Trial/Study per site.
5.3.1.4. ICH E6 uses the word **Investigator** to describe the individual responsible for the conduct of a Clinical Trial/Study at a site.

5.4. **Principal Investigator:** Commonly used to refer to a person responsible for the conduct of the Clinical Trial/Study at a Study Site. If a Clinical Trial/Study is conducted by a team of individuals at a Clinical Trial/Study site, the Principal Investigator is the responsible leader of the team. Often used interchangeably with Qualified Investigator, which is Health Canada terminology, though Principal Investigator is not a legally defined term used in Canada.

5.4.1. **Please note that VCHRI SOPs Version 3 use the term 'Principal Investigator' (PI) to refer to Qualified Investigator and Investigator.**

5.5. **Sub-Investigator**: A qualified member of the clinical research team designated and supervised by the Principal Investigator or Sponsor-Investigator at a Clinical Trial/Study site to perform critical study or trial-related procedures and/or to make important study-related decisions (usually a licensed physician, associate, resident, research fellow or nurse).

5.6. **Clinical Research Coordinator:** 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/Study. The Clinical Research Coordinator acts as liaison between the Clinical Trial/Study Site and the Sponsor/Sponsor-Investigator and ensures review of all data and records before a Monitor's visit and performs designated Participant assessments.

5.7. **Research Team Member**: Clinical research personnel that are qualified by training and experience to conduct Clinical Trial/Study tasks and activities on behalf of the Principal Investigator and the Institution. Research Team Members include Clinical Research Coordinators, Sub-Investigators, research nurses and research assistants.

5.8. See also VCHRI Glossary of Terms.

6. PROCEDURE

6.1. Creation of a Research Team

6.1.1. All Research Team Members must understand the responsibilities of the Clinical Trial/Study site, and be appropriately qualified by education, training and experience to perform their study-related task(s).

6.1.2. In preparation for a Clinical Trial/Study, the Principal Investigator or delegate(s) should:

6.1.2.1. Appoint members of the research team who will be involved in the Clinical Trial/Study (before submitting to the Research Ethics Board, where applicable);

6.1.2.2. Determine, at the beginning of the Clinical Trial/Study, each Research Team Member's role, and the availability of relief Research Team Members;

6.1.2.3. Identify Research Team Members who require training on Good Clinical Practice and other applicable regulations and guidelines;

6.1.2.4. Schedule training on Protocol content and application; and

6.1.2.5. Maintain a list of appropriate qualified persons who have been delegated significant study-related tasks.

6.1.3. The Principal Investigator/Sponsor-Investigator must ensure that all persons assisting with the Clinical Trial/Study are adequately informed and trained on the Protocol, Investigational Product (as applicable), Medical Device (as applicable), and their study-related duties and functions, and that this training is documented.

6.2. Roles and Responsibilities of the Sponsor

6.2.1. The Sponsor is responsible for ensuring that:

6.2.1.1. The Clinical Trial/Study is scientifically sound and clearly described in a Protocol;

6.2.1.2. The Clinical Trial/Study is conducted, and the Investigational Product, if applicable, is used in accordance with the Protocol;

6.2.1.3. Systems and procedures that assure the quality of every aspect of the Clinical Trial/Study are implemented;

6.2.1.4. The methods used to assure and control the quality of the trial are risk based and should focus on activities that ensure human subject protection and the reliability of trial results;

6.2.1.5. The approval of a Research Ethics Board is obtained before the Clinical Trial/Study begins at the study site;

6.2.1.6. There is no more than one Principal Investigator at each Clinical Trial/Study site;

6.2.1.7. Medical care and medical decisions associated with the Clinical Trial/Study are under the supervision of the Principal Investigator;

6.2.1.8. Each individual involved in the conduct of the Clinical Trial/Study is qualified by education, training and experience to perform his or her respective tasks;

6.2.1.9. Any Clinical Trial/Study-related duties and functions carried out on its behalf (e.g. by a CRO; vendor) are specified in writing, and that there is Sponsor oversight of those activities;

6.2.1.10. 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/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 Trial/Study, and all other aspects of the Clinical Trial/Study that are necessary for that person to make an informed decision to participate in the Clinical Trial/Study;

6.2.1.11. The requirements respecting information and records set out in Part C, Division 5 of the Canadian Food and Drug Regulations and/or Part 3 of the Medical Devices Regulations are met (if applicable); and

6.2.1.12. The drug(s) is/are manufactured, handled and stored in accordance with the applicable Good Manufacturing Practice (GMP) regulations of Health Canada (if applicable).

6.3. Roles and Responsibilities of the Sponsor-Investigator

6.3.1. The obligations of a Sponsor-Investigator include both those of a Sponsor and those of a Principal Investigator.

6.4. Roles and Responsibilities of the Principal Investigator

6.4.1. The Principal Investigator is responsible for the safety and well-being of Participants, the conduct of the Clinical Trial/Study, administration of the Investigational Product, if applicable, team and space requirements, conformity with the requirements of the Research Ethics Board, and GCP team training.

6.4.2. Although some of these tasks may be delegated to other qualified Research Team Members, the Principal Investigator should ensure the individual or party is qualified to perform those study tasks and is responsible for supervising any individual or party to whom tasks are delegated at the trial site. The Principal Investigator assumes ultimate responsibility for the overall conduct of a Clinical Trial/Study at the site level, and for compliance with all applicable regulations and guidelines. The Principal Investigator must document the delegation of tasks/duties (see Section 6.7).

6.4.3. The Principal Investigator must:

6.4.3.1. Be qualified by education, training, and experience to assume responsibility for the proper conduct of the Clinical Trial/Study at the site level, meet all the qualifications specified by the applicable regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and other relevant documentation requested by the Sponsor, the Research Ethics Board and the Regulatory Authorities;

6.4.3.2. Be thoroughly familiar with the appropriate use of the Investigational Product as described in the Protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by Sponsor or Sponsor-Investigator;

6.4.3.3. Be aware of and comply with GCP and other applicable regulatory requirements:

6.4.3.3.1. Drugs: Part C, Division 5 of the Food and Drug Regulations

6.4.3.3.2. Medical Devices: Part 3 of the Medical Device Regulations

6.4.3.3.3. Natural Health Products: Part 4 of Natural Health Products Regulations

6.4.3.4. Permit and facilitate monitoring and auditing of the Clinical Trial/Study and by the Sponsor, Institution, and Inspection by the appropriate Regulatory Authorities;

6.4.3.5. Unless delegated to a qualified and trained sub-Investigator, make and document study-related medical decisions including review/assessment of laboratory and imaging results for clinical significance, and assessment/determination of causality for Adverse Events etc.; and

6.4.3.6. Formulation of Participant treatments plans, decisions on dose adjustments and guidance on any supportive care, as applicable.

6.4.4. The Principal Investigator must also ensure that:

6.4.4.1. All persons assisting with the Clinical Trial/Study are qualified and adequately trained, including Clinical Trial/Study specific education and training in Good Clinical Practices;

6.4.4.2. All persons assisting with the Clinical Trial/Study are adequately informed about the Protocol, Investigational Product and their study-related tasks and roles;

6.4.4.3. Adequate medical care is provided to a Participant in the case of any Adverse Event or Medical Device Incident;

6.4.4.4. A written and dated approval/favourable opinion from the Research Ethics Board for the Protocol, written Informed Consent Form, consent form updates, Participant recruitment

procedures (e.g., advertisements) and any other written information to be provided to Participants has been granted before the Clinical Trial/Study is begun at the Study Site;

6.4.4.5. The Clinical Trial/Study is conducted in compliance with the Protocol approved by the Sponsor or Sponsor-Investigator, the Research Ethics Board and, if applicable, appropriate Regulatory Authorities, such as Health Canada;

6.4.4.6. He/she makes all study-related medical decisions unless delegated to a qualified and trained Sub-Investigator;

6.4.4.7. The data reported to the Sponsor or Sponsor-Investigator in the Case Report Forms and in all required reports are accurate, complete and timely;

6.4.4.8. All Clinical Trial/Study documents are maintained and updated as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements (see ICH E6 Section 8.0);

6.4.4.9. Necessary measures are taken to prevent accidental or premature destruction of Essential Documents; and

6.4.4.10. All Serious Adverse Events are immediately reported to the Sponsor, REB, Institution and/or applicable Regulatory Authorities within the required time frames as outlined in the Protocol and as per Health Canada safety reporting guidelines.

6.4.5. Responsibility for Investigational Product at the Clinical Trial/Study Site rests with the Principal Investigator (and Institution, as applicable). The Principal Investigator should ensure that the Investigational Product is used only in accordance with the approved Protocol. Where allowed/required, the Principal Investigator (or Institution, as applicable) may/should assign some or all of the Principal Investigator/Institution's tasks for the 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 Principal Investigator/Institution.

6.4.6. The Principal Investigator or a person designated by the Principal Investigator should explain to each Participant the appropriate use of the Investigational Product and should verify, at regular intervals, if all Participants are following instructions appropriately.

6.4.7. For Health Canada Division 5 regulated trials only: The Qualified Investigator 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 Qualified Investigator per study per site. If an Investigational New Drug (IND) application for the Investigational Product has been submitted to the US, a Form FDA 1572 may need to be completed, or the sponsor can request a waiver for the Canadian site, as per UBC REB guidance. By signing these forms, the Qualified Investigator agrees to conduct the Clinical Trial/Study in accordance with any other applicable regulations and guidelines, and acknowledges his/her responsibilities as defined by the regulatory bodies.

6.5. Roles and Responsibilities of the Clinical Research Coordinator

6.5.1. The Clinical Research Coordinator works in collaboration with the Principal Investigator, and with a multidisciplinary research team to ensure that high Clinical Trial/Study standards are maintained. The Clinical Research Coordinator, in collaboration with the Principal Investigator, assesses the skills required to conduct his/her role, and obtains the necessary training, for each Protocol.

6.5.2. The specific roles of the Clinical Research Coordinator are described in the procedures of each SOP. However, in general the Clinical Research Coordinator (alone or with the assistance of other Research Team Members):

6.5.2.1. Works closely with the Principal Investigator and Sponsor/Sponsor-Investigator to organize, plan and carry out the Clinical Trial/Study in an efficient and timely manner including: preparing the Research Ethics Board submission; providing Participants with all pertinent information regarding the Clinical Trial/Study; coordinating Participant appointments and monitoring visits; executing Clinical Trial/Study-related procedures with the authorization of the Principal Investigator; organizing source and Essential Documents; completing Case Report Forms, and ensuring that Case Report Form entries are consistent with source documents;

6.5.2.2. Liaises with applicable hospital departments (laboratory, pharmacy, radiology etc.) and Research Ethics Board;

6.5.2.3. Adheres to GCP and regulatory guidelines, regulations, and Standard Operating Procedures, and remains current on guidelines, regulations and Standard Operating Procedures by attending or obtaining training as required.

6.6. Roles and Responsibilities of Other Parties

6.6.1. Other parties may be involved in generating Clinical Trial/Study data (e.g., research and testing laboratories, pharmacy etc.). The Principal Investigator should ensure the party is qualified to perform those study tasks and implement procedures to ensure the integrity of the study tasks performed and any data generated. At the request of the Principal Investigator, these parties must be added to the task delegation log.

6.6.1.1. Internal groups (e.g. departments within the Institution): A supervisor is usually required to be listed on the task delegation log.

6.6.1.2. External vendors: The Principal Investigator must ensure appropriate surveillance and oversight of external vendors.

6.6.2. During a Clinical Trial/Study, the pharmacist may have an active role, if required by the Protocol. Study medication can be prepared, distributed, and stored by the pharmacy. Moreover, delivery, dispensing to Participants, recording and, if necessary, disposal of the study medication, can all be managed by the pharmacist.

6.6.3. For medical device studies, Biomedical engineering, risk management or departments such as the operating room, may be involved and may need to conduct their own assessment for use at the Institution.

6.7. Documentation of Task Delegation

6.7.1. The Principal Investigator or Sponsor-Investigator may delegate certain tasks to qualified members of the clinical research team, but the Principal Investigator or Sponsor-Investigator remains ultimately responsible for providing adequate supervision of those Research Team Members to whom tasks have been delegated, and for ensuring that each task has been delegated appropriately.

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

6.7.2.1. Names of team members printed clearly or typed;

6.7.2.2. Dated signature and initials of each team member;

6.7.2.3. Task specification or roles delegated;

6.7.2.4. Start and end dates of delegation; and

6.7.2.5. Signature of the Principal Investigator.

6.7.3. The signatures and initials of all persons authorized to make entries and/or corrections on Case Report Forms, must be recorded to permit an evaluation of the conduct of the Clinical Trial/Study and the quality of the data.

6.7.4. If the delegation log is to be used as the Clinical Trial/Study signature log, the Principal Investigator must sign for each individual to whom he/she has delegated responsibility.

7. REFERENCE(S)

BC Freedom of Information and Protection of Privacy Act, [RSBC 1996, c. 165], as amended from time to time.

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 2014.

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

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

Health Canada, Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects". GUI-0100. August 20, 2019.

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

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), November 9, 2016.

Network of Networks (N2) Research Team Roles and Responsibilities, SOP002_09. Effective Date 15-May-2021.

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

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

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).

8. ATTACHMENT(S)

None.