

1. Purpose

The purpose of this SOP is to outline the tasks and activities associated with the activation of research sites in trials managed by CERU.

2. Responsibilities

CERU: CERU is responsible for ensuring the research site meets all requirements prior to activation.

3. Procedures

- 3.1 Following determination that a particular research site will participate in a CERU managed trial (refer to SOP 205: Site Selection & Qualifications) the following tasks and activities must be completed before the site is officially activated.
- 3.2 Site activation refers to the point in time when the site is ready to begin patient recruitment activities.

Canadian Sites

- 3.3 The following regulatory documentation must be in place at CERU for Canadian research sites:
 - 3.3.1 Letter of No Objection to commence study, if applicable
 - 3.3.2 Health Canada, Therapeutic Products Directorate documents, if applicable
 - 3.3.2.1 Qualified Investigator Undertaking
 - 3.3.2.2 Research Ethics Board Attestation, or comparable document
 - 3.3.2.3 Clinical Trial Site Information
 - 3.3.3 Notification to Health Canada regarding the participation of research site, including Clinical Trial Site Information Form
 - 3.3.4 Fully executed Site Agreement
 - 3.3.5 Research Ethics Board Approval, including informed consent form
 - 3.3.6 Confirmation that the Qualified Investigator is licensed to practice medicine in the applicable Province/Territory.
 - 3.3.7 Curriculum Vitae for Qualified Investigator
 - 3.3.8 Local laboratory accreditation and reference ranges

United States Sites

- 3.4 The following regulatory documentation must be in place at CERU for research sites located in the United States:
 - 3.4.1 Documents as described in sections 3.3.4, 3.3.5, 3.3.6, 3.3.7 and 3.3.8.
 - 3.4.2 Investigational New Drug (IND) letter from the Food & Drug Administration (FDA), if applicable.
 - 3.4.2.1 FDA documents, if applicable:
 - 3.4.2.1.1 Completed FDA 1572 Statement of Investigator

- 3.4.2.1.2 Completed FDA 3455 Disclosure: Financial Interests and Arrangements of Clinical Investigators
- 3.4.3 Confirmation the Qualified Investigator is licensed to practice medicine in the applicable state
- 3.4.4 Confirmation the Qualified Investigator has not been disqualified or restricted by the FDA (refer to the FDA Disqualified/Restricted/Restrictions Removed/Assurance Lists for Clinical Investigators list found on the FDA website).

Sites Outside of Canada and the United States

- 3.5 The following regulatory documentation must be in place at CERU for research sites located outside of Canada and the United States:
 - 3.5.1 Documents as described in sections 3.3.4, 3.3.5, 3.3.6.
 - 3.5.2 Study Approval documentation from the relevant regulatory body, if applicable.
 - 3.5.3 Other associated documents required by the relevant regulatory body, if applicable.
- 3.6 In addition to documents in 3.3, 3.4 or 3.5, the following activities must be completed for all research sites:
 - 3.6.1 CERU will complete study specific training of Qualified Investigator and delegated individuals (i.e. Research Coordinator, Pharmacist, Lab personnel, etc...). Training includes, but is not limited to:
 - 3.6.1.1 Study Protocol
 - 3.6.1.2 Objectives and Procedures
 - 3.6.1.3 Participant inclusion and exclusion
 - 3.6.1.4 Consent procedures
 - 3.6.1.5 Investigational Product (administration and management)
 - 3.6.1.6 Regulatory obligations of the site
 - 3.6.1.7 Procedures for reporting adverse events
 - 3.6.1.8 Data collection & entry
 - 3.6.1.9 Data management activities
 - 3.6.1.10 Required regulatory documentation
 - 3.6.2 Confirmed shipment of Investigational Product
 - 3.6.3 Confirmed shipment of Laboratory Supplies, if applicable
- 3.7 If an electronic data capture system (EDCS) is being used for the trial, the following must occur:
 - 3.7.1 Establishment of the research site profile (i.e. Institution name, site number)
 - 3.7.2 Establishment of individual user access to EDCS for responsible individuals (e.g. research coordinator and pharmacy).
- 3.8 Once the criteria in sections 3.3-3.7 has been satisfied, the study Project Leader, or delegate, will prepare a communication to the site (refer to Appendix 4.1: Site Activation Checklist), confirming the research site is considered activated and may begin patient recruitment.

4. Appendix

4.1 Site Activation Checklist

5. References

5.1 ICH GCP Section 8.0: Essential Documents for the Conduct of a Clinical Trial

5.2 Health Canada Division 5 Food and Drug Regulations: Drugs for Clinical Trials Involving Human Subjects

5.3 Network of Networks Standard Operating Procedures for Clinical Research ([N₂ organization](#)).



Site Activation Checklist

Study Title:	
Principal Investigator:	
Research Site:	
Qualified Investigator:	

Activity	Y	N	N/A	Comments
Regulatory Documentation (Research sites in Canada)				
1. Health Canada				
a. Letter of No Objection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Qualified Investigator Undertaking (QIU)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Research Ethics Board Attestation (REBA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Clinical Trial Site Information (CTSI) form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Notification to Health Canada	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Fully Executed Site Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Research Ethics Board Approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Confirmation the Qualified Investigator is licensed to practice medicine in the applicable Province/Territory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Curriculum Vitae for Qualified Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Local laboratory accreditation and reference ranges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Regulatory Documentation (Research sites in the United States)			
1. Fully Executed Site Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Research Ethics Board Approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Curriculum Vitae for Qualified Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Confirmation the Qualified Investigator is licensed to practice medicine in the applicable state	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Confirmation the Qualified Investigator has not been disqualified or restricted by the FDA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Investigational New Drug (IND) letter from the FDA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a) FDA 1572 Statement of Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) FDA 3455 Disclosure: Financial Interests and Arrangements of Clinical Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Local laboratory accreditation and reference ranges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training			
1. Research Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Pharmacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Site Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Lab Technicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Dietician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Completed by:

Name

Date