

1. Purpose

The purpose of this SOP is to outline the procedures CERU should follow when engaging in operational activities for an external sponsor.

2. Responsibilities

External Sponsor: The External Sponsor is responsible for the overview of all trial-related activities.

CERU: CERU is responsible for conducting activities, mutually agreed upon with the External Sponsor, according to ICH GCP and all applicable regulatory requirements.

3. Procedures

External Sponsor: An External Sponsor is an individual or organization enlisting the services of CERU to manage the operations of a study. An External Sponsor does not have any affiliation with CERU, but may have collaborated with CERU on previous research projects.

- 3.1 Prior to agreeing to manage a trial for an External Sponsor, a decision must be made if performing this trial is in the best interests of CERU.
- 3.2 To make this decision, the Director of CERU in conjunction with appropriate CERU staff will:
 - 3.2.1 Perform a review of the scientific value of the study.
 - 3.2.2 Conduct a review of CERU staff experience in the field of the proposed trial.
 - 3.2.3 Review the proposed budget and timelines to ascertain CERU resource availability.
 - 3.2.4 Review the proposed protocol to determine patient population, number and type of sites required, and the proposed duration of the study.
 - 3.2.5 Review the Investigator's Brochure for the Investigational Product.
- 3.3 The decision process will be documented using the Study Evaluation Questionnaire (Appendix 4.1)
- 3.4 If the decision is made to proceed forward with the External Sponsor the following should occur:
 - 3.4.1 A service agreement will be created by CERU, and presented to the External Sponsor for review. Refer to SOP 213: Academic Research Organization Service Agreements.
 - 3.4.2 A finalized protocol and Product Monograph will be provided to CERU by the External Sponsor.
- 3.5 Study Startup activities will be performed by CERU, as outlined in the Delegation of Responsibilities Checklist (refer to SOP 213 – Academic Research Organization Service Agreements), in accordance with CERU 200 series SOPs.
- 3.6 Corresponding tools will be developed for the study, based on the needs of the External Sponsor.
- 3.7 CERU shall communicate with the External Sponsor regularly throughout the duration of the trial to ensure the trial is being conducted according to the Protocol and Service Agreement.

4. Appendix

4.1 Study Evaluation Questionnaire

5. References

5.1 ICH GCP Section 5.0: Sponsor

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](#)).



Study Evaluation Questionnaire

Name of Study:

PART A: External Sponsor Contact Details		
Last Name:		First Name:
Company:		Affiliated University:
Address:		Tel:
City		Fax:
Province/State:		Email:
Postal/Zip Code:		Best Method of Contact:
Studies performed for this Sponsor in the past:		
PART B: Study Details		
1	Sample Size	
2	Intervention	<input type="checkbox"/> Pharmacological <input type="checkbox"/> Procedure <input type="checkbox"/> Device <input type="checkbox"/> Other: _____ <input type="checkbox"/> None
3	Indication	
4	Study Design	<input type="checkbox"/> RCT <input type="checkbox"/> Observational <input type="checkbox"/> Multicentre <input type="checkbox"/> Pilot <input type="checkbox"/> Other: _____
5	Intended Study Population:	
6	Anticipated number of sites:	
7	Type of unit required:	<input type="checkbox"/> ICU - Neuro <input type="checkbox"/> ICU - Med/Surg <input type="checkbox"/> ICU - Trauma <input type="checkbox"/> Other: _____ <input type="checkbox"/> Other: _____
8	Is there an Investigational Product? If yes, is the Investigational Product being used outside of the current marketing approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	Has funding been secured?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, is the funding adequate for CERU resources?	<input type="checkbox"/> Yes <input type="checkbox"/> No
10	In what regions is the study anticipated to be conducted?	<input type="checkbox"/> Canada <input type="checkbox"/> US <input type="checkbox"/> EU, Specify: _____ <input type="checkbox"/> Other: _____
	Who will be handling the regulatory approvals in these regions?	<input type="checkbox"/> CERU <input type="checkbox"/> External Sponsor
11	Who will be responsible for SAE reporting and processing?	<input type="checkbox"/> CERU <input type="checkbox"/> External Sponsor
	Who will be responsible for reporting adverse drug reactions to the appropriate governing regulatory bodies?	<input type="checkbox"/> CERU <input type="checkbox"/> External Sponsor



Part C: Study Validity		
1	Is the study population feasible (not too small, rare, difficult to recruit)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Are the study interventions supported by scientific evidence?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	Are the outcomes measurable?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	Is the study protocol scientifically sound?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Part D: CERU Resource Assessment		
1	Does the study compete for patients with current open CERU studies or other studies actively recruiting patients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Current number of CERU projects in progress.	
3	Does CERU have experience in this field of study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	Is there interest at CERU in this field of research?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5	Is there sufficient staff available at CERU?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Part E: Data Management Considerations		
1	Data elements established?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Statistical consulting services required?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	CRF Format	<input type="checkbox"/> Electronic <input type="checkbox"/> Paper

Evaluation Completed by:

Name

Signature

Date

Comments: