



1. Purpose

The objective of this operating procedure is to clearly outline the qualifications that should be met before a site is considered suitable for participation in a study.

2. Responsibilities

CERU Project Leader: The CERU Project Leader, under the guidance of the Sponsor, is responsible for ensuring potential investigators are suitably qualified to participate in a research study.

Qualified Investigator (QI): is responsible for selecting suitably qualified site personnel to perform study related tasks and functions.

3. Procedures

- 3.1 The CERU Project Leader, under the guidance of the Sponsor, will assess the suitability of the research site to participate in the study by communicating with the QI and site research staff. This will be based on the following:
- 3.1.1 Interest in the scientific aspects of the study.
 - 3.1.2 Being qualified by training and experience to properly conduct the study.
 - 3.1.3 Having sufficient time free from other obligations to prepare and conduct the study.
 - 3.1.4 Ability and willingness to conduct the trial according to ICH GCP and the governing regulations in the participating country.
 - 3.1.5 Adequate site research personnel and facilities, including but not limited to, dedicated research coordinator, adequate pharmacy staff and adequate laboratory resources.
 - 3.1.6 Compatibility with local healthcare practice
 - 3.1.7 Agreement to comply with the protocol and any subsequent amendments.
 - 3.1.8 Agreement to obtain the favorable opinion of the local Research Ethics Board prior to commencement of any patient related activities.
 - 3.1.9 Ability to comply with time-sensitive responsibilities as outlined in the signed Site Agreement
 - 3.1.10 Ability to accommodate site visits at mutually agreeable dates and times.
 - 3.1.11 Ensuring sufficient medical staff to support the study
- 3.2 Prior to finalizing any formal agreement regarding the participation of the research site, CERU Project Leader should provide the QI with the protocol, a current Investigator's Brochure or Product Monograph, and sufficient time for the QI to review the information provided.
- 3.3 The CERU Project Leader will conduct a pre-study site visit or teleconference to ascertain the investigator and site qualifications. This assessment will be documented on the Site Screening Questionnaire (refer to Appendix 4.1).



Site Selection & Qualifications
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- 3.4 A pre-study site visit/teleconference may be waived based on previous experience with other CERU projects or for other reasons as specified by the Sponsor. Waiver of the site selection process will be documented on the Site Screening Waiver Form (refer to Appendix 4.2).
- 3.5 The Sponsor, or delegate, will approve or disapprove of a potential investigator based on the results of the site screening process.
- 3.6 If both CERU and the QI/Research Site agree to the site participating in the research study, the agreement will be put in writing (see SOP 206: Generation and Distribution of Agreements).

4. Appendix

- 4.1 Site Screening Questionnaire
- 4.2 Site Screening Waiver Form

5. References

- 5.1 ICH GCP Section 4.1: Investigator Qualifications and Agreements
- 5.2 ICH GCP Section 4.2: Adequate Resources
- 5.3 ICH GCP Section 5.6: Investigator Selection



Site Screening Questionnaire

Dr. <<name>> along with the Clinical Evaluation Research Unit (CERU) at Queen's University would like to assess your interest in participating as an investigator in the <<Study>>, a clinical trial examining <<brief study description>>.

We request that this questionnaire is completed by the physician or delegated research team member.

Return completed questionnaires to the CERU project office:
 Email:<<PL email>> OR Fax: + 613 548 1351

| PART A: Physician Contact Details | | | |
|-----------------------------------|--|-------------------------|--|
| Last Name: | | First Name: | |
| Affiliated Hospital: | | Affiliated University: | |
| Address: | | Tel: | |
| City | | Fax: | |
| Province/State: | | Email: | |
| Postal/Zip Code: | | Best Method of Contact: | |

| PART B: ICU Demographics | | |
|--------------------------|--|--|
| 1 | Type of institution: | <input type="checkbox"/> Academic <input type="checkbox"/> Community |
| 2 | Administrative Structure: | <input type="checkbox"/> Open <input type="checkbox"/> Closed |
| 3 | ICU Population: | <input type="checkbox"/> Neuro <input type="checkbox"/> Med/Surg <input type="checkbox"/> Trauma |
| 4 | Number of ICU beds: | |
| 5 | Number of patients admitted to the ICU annually: | |

| Part C: Clinical Trials Expertise and Resources | | |
|---|--|---|
| 1 | Is the physician and research team familiar with Good Clinical Practice Guidelines for conducting clinical trials? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2 | How many studies are ongoing at your site? Please list the type of studies (e.g. ARDS, Nutrition, VAP): 1) _____ <input type="checkbox"/> Industry <input type="checkbox"/> Academic 2) _____ <input type="checkbox"/> Industry <input type="checkbox"/> Academic 3) _____ <input type="checkbox"/> Industry <input type="checkbox"/> Academic 4) _____ <input type="checkbox"/> Industry <input type="checkbox"/> Academic 5) _____ <input type="checkbox"/> Industry <input type="checkbox"/> Academic | # studies: ____ |
| 3 | Will you be available for oversight of study patients? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4 | Will you be available for resolution of issues pertaining to the study? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5 | Will the investigator be available for regulatory and essential document signatures? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6 | Are you planning to use any sub-investigators? If yes, please list: 1) _____ 2) _____ 3) _____ 4) _____ | <input type="checkbox"/> Yes <input type="checkbox"/> No |



Site Screening Questionnaire

| | | |
|-------------------|--|---|
| 7 | Do you have a research coordinator? If yes, please list contact details: | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8 | Has your site ever been audited by Health Canada, US FDA or other regulatory agency? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9 | How often does your REB meet? | <input type="checkbox"/> Weekly <input type="checkbox"/> Bi-weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly |
| 10 | Does your Pharmacy have resources to support research activities (e.g. randomization, mixing study product, study product accountability)? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 11 | Do you have a -70 °C freezer? If no, a -20 °C freezer? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No |
| PART D: <<Study>> | | |
| 1 | <<Study specific question...>> | |
| 2 | | |
| 3 | | |
| 4 | | |

Please attach a copy of the physician's CV when forwarding the questionnaire responses.

Thank you for taking the time to complete this questionnaire.



Site Screening Waiver Form

| | |
|---------------------------------|--|
| Title of Study: | |
| Sponsor/Principal Investigator: | |
| Project Leader: | |
| Research Site: | |
| Site Investigator: | |

Rationale for Site Screening Waiver:

Sponsor / Project Leader Signature

Date