



Site Selection & Qualifications 205-00

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

Methods Centre (MC): The MC, 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 MC, 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 Agreement to comply with the protocol and any subsequent amendments.
 - 3.1.7 Agreement to obtain the favorable opinion of the local Research Ethics Board prior to commencement of any patient related activities.
 - 3.1.8 Ability to comply with time-sensitive responsibilities as outlined in the signed Site Agreement
 - 3.1.9 Ability to accommodate site visits at mutually agreeable dates and times.
 - 3.1.10 Ensuring sufficient medical staff to support the study
- 3.2 Prior to finalizing any formal agreement regarding the participation of the research site, the Sponsor 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 MC 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 1).
- 3.4 A pre-study site visit/teleconference may be waived based on previous experience with other MC studies 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 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 the MC 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



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- 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