EFFECTIVE DATE: January 2024

To outline the activities required to facilitate all study start-up requirements. A streamlined start-up process allows for quick timelines, proper study management, subject safety, and compliance with internal and external requirements.

This Standard Operating Procedure applies to all USA personnel involved in the startup of a clinical trial. It covers from the time the Sponsor makes contact with the Investigator about a potential trial to when the trial is activated and ready to enroll.

Also called Non-Disclosure Agreement (NDA). A contract between the study sponsor and the institution that governs the access and use of confidential information, which includes the study protocol and other proprietary business or scientific information.

This visit may go by numerous other names such as Pre-Site Visit (PSV) or Site Selection Visit (SSV). The Site Qualification Visit (SQV) is the process by which the study

11. Review the Informed Consent Form in detail.
    11.1. Compare against the protocol for accuracy
    11.2. Edit to maintain 6th-8th grade reading level
    11.3. Ensure required elements are present
    11.4. Insert or edit USA required language
    11.5. All revisions to the consent should be tracked and sent to the sponsor/CRO for negotiation and approval.
    11.6. Refer to CT 401 of additional guidance on the Informed Consent Form.

12. Prepare and submit documents to the Institutional Review Board (IRB). Use the governing Institutional Review Board's SOP for further instructions on what to submit, how to submit, and who to submit to.

13. Create source worksheets, as needed, using at least the protocol and Case Report Form (CRF).

14. Complete sponsor and/or protocol specific training, as applicable.

15. For studies conducted on an in-patient basis, or as applicable, all floor nurses, research pharmacy personnel, residents, attending physicians, infusion nurses, Fellows, lab technicians, pathology personnel, etc. who will be involved either directly or indirectly, delegated or not delegated, will need to be made aware of the study to enrolling the first subject. Documentation of training should be documented per CT205 Training Record. Provide each relevant department with a research contact.

16. Delegated research and ancillary staff must be trained, in detail, on the study and associated procedures to enrolling the first subject. Training must be documented and placed in the regulatory binder.

17. Verify that all study materials have been received. Examples include sponsor provided equipment, investigational product, lab supplies, etc.

18. Verify that access has been obtained to all systems i.e. Interactive Voice Recognition System (IVRS), Electronic Data Capture system (EDC), Firecrest, etc. for all applicable personnel.

19. Verify that the budget and Clinical Trial Agreement (CTA) have been fully executed and that the Institutional Review Board (IRB) has approved the study to enroll.

20. Schedule and conduct a Site Initiation Visit (SIV). SIV should occur after all IRB approval and CTA execution, unless otherwise approved by the Clinical Trials Office Director.

21. Complete study delegation log. Refer to CT206 for guidance.

22. No protocol specific activity may begin prior to receiving IRB approval and an activation letter from the study sponsor.
    22.1. Upcoming studies may be discussed with potential participants, however discussions should be limited to publicly available information, such as information available on ClinicalTrials.gov or other public databases.

CT 103 Qualified Investigators & Staff
CT 201 Regulatory Documents
CT 205 Protocol Training Records
CT 206 Delegation Log
CT 301 Feasibility Analysis
CT 401 Informed Consent

Informed Consent Form Checklist
Start-up checklist
Initial Study Feasibility Assessment

Coverage Analysis
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N/A

January 2027

Director, Clinical Trials Office