UNIVERSITY OF SOUTH ALABAMA

CT 302 STUDY START-UP PROCEDURES

EFFECTIVE DATE: January 2024

Purpose

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.

Scope

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.

Definitions

Confidential Disclosure Agreement: 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.

Site Qualification Visit: 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 sponsor and/or clinical research organization determine whether the investigator and the clinical site have the resources and capabilities necessary to conduct the study. This visit occurs prior to entering an agreement to conduct the study at the site.

University of South Alabama: For the context of this Policy and Procedure, all activities referred to as pertaining to the University of South Alabama encompasses USA and USA Health Systems.

Procedures

1. When first approached for a new study, a Confidential Disclosure Agreement (CDA) will need to be reviewed and approved by University of South Alabama legal or a Contracts Administrator.. A master or blanket CDA may already be in place which would eliminate the need for a study specific CDA. Any CDA for a new study must be signed by a Signature Authority and not just the Principal Investigator (PI) or research staff

2. Obtain the basic study information from the study sponsor. Attempt to obtain a full protocol.

3. Complete all feasibility assessments
   3.1. Assessment of the site as required by the sponsor
   3.2. Study assessment outlined in CT 301 should be followed.

4. Schedule a Site Qualification Visit (SQV) if applicable
   4.1. Attempt to obtain a full protocol prior to SQV if not previously obtained
   4.2. Compile a list of questions to ask at the SQV

5. Re-evaluate the study assessment based on the information provided at the SQV. The PI and/or department should make a decision to proceed with the study or not. Notify the sponsor and any applicable USA personnel if the decision is to not participate.

6. If selected for the study, obtain all applicable start-up documents. Such documents may include:
   6.1. Protocol
   6.2. Investigator Brochure
   6.3. Informed Consent Form
   6.4. 1572 template
   6.5. Clinical Trial Agreement
   6.6. Budget
   6.7. Financial Disclosure templates
   6.8. Recruitment/Advertisement materials

7. Disseminate start-up documents to appropriate USA personnel for tasks such as:
   7.1. Coverage analysis
   7.2. Contract negotiations
   7.3. Budget negotiations
   7.4. Constructing the study in various computer systems

8. Complete regulatory documents. Completed documents should be sent to the sponsor/CRO. All completed documents must be saved in the site regulatory file, as outlined in CT 201.

9. A conversation should be had to determine what research staff will be involved on the study and what task they need to be delegated. Hospital and other USA resources will need to be determined. Such a conversation should include, as applicable, the study coordinator(s), research manager, regulatory coordinator, and investigator.

10. Present the study at any ancillary committees, as applicable.

11. Review the Informed Consent Form in detail.
    11.1. Compare against the protocol for accuracy
    11.2. Edit to maintain 6^{th}-8^{th} 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 **prior** 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 **prior** 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.

Additional Resources

RELATED SOPS:
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

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

RELATED POLICIES
Coverage Analysis
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History

N/A

Next Review Date

January 2027

Responsible Party

Director, Clinical Trials Office