UNIVERSITY OF SOUTH ALABAMA

CT-301 FEASIBILITY ANALYSIS

EFFECTIVE DATE: August 2023

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe pre-agreement procedures for assessing feasibility of conducting a specific study at the University of South Alabama's Clinical Trials Office.

Scope

This SOP applies to all clinical studies conducted through the University of South Alabama Clinical Trials Office. The Principal Investigator (PI), in conjunction with other appropriate scientific and/or business personnel will assess whether or not it would be feasible to conduct the protocol and if the protocol is scientifically sound and the study has intrinsic merit.

Definitions

Confidential Disclosure Agreement (CDA): 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.

Principal Investigator: The individual of record who assumes the authority and responsibility for the conduct of a clinical study.

Sponsor: When a clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor. When a clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority over the trial, will be considered the sponsor.

Policy

Before agreeing to participate in a clinical research study, the Principal Investigator (PI) and the USA CTO must determine the feasibility of the study. Together, they should assess the study proposal, considering:

- ethics,
- investigator site capabilities (i.e.: equipment; facilities; staff),
- clinical feasibility and scientific merit,
- business practicality,
- enrollment capability

Study feasibility should be completed after a full protocol has been received and prior to the Site Initiation Visit.

Procedures

The appended feasibility checklist may be used as a guide to facilitate conversations and determinations on whether or not the site can and should participate in the proposed study.

1. A nondisclosure agreement/confidential disclosure agreement (NDA or CDA) is generally required in order to obtain the protocol and study documents from the Sponsor for assessment review. This is required to be sent to the USA Sponsored Projects Administration (SPA) for review and execution.

2. Protocol review should be carried out as soon as is practical after the investigator receives a copy of the protocol. Feedback regarding the suitability of study acceptance should be given to the Sponsor at the earliest opportunity. Discuss issues identified regarding the protocol that may impact recruitment, safety, logistics, etc.

3. Documents should be requested from the sponsor to perform a comprehensive study assessment. Such documents may include:
   3.1. Protocol
   3.2. Informed Consent Form
   3.3. Investigator Brochure
   3.4. Source worksheets
   3.5. Case Report Form

4. The PI and/or department is responsible for ensuring adequate consideration & review of a protocol tendered by a Sponsor.

5. Review should be carried out by individuals with the appropriate expertise: this may include a Study Site Coordinator, Study Nurse, Research Administrator, financial reviewer, Feasibility Committee, others. Review of the protocol should ensure the following:
   - The study objectives are clear.
   - The study design is feasible.
   - The study will not expose subjects to undue risk.
   - The study is ethically acceptable.
   - The study is financially and logistically feasible.

- The site can properly store the investigational product.
- There are a sufficient number of potential subjects available for the study.
- There is sufficient & qualified staff to conduct the study.
- The site has the appropriate equipment to conduct the study.
- Adequate medical care will be provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial.
- The investigator will have sufficient time to properly conduct and complete the trial within the agreed trial period considering other time commitments.
- Potential real or perceived Conflicts of Interest between study personnel and study conduct are identified, and may be reasonably managed.
- Impediments to IRB approval are identified and resolved.
- Anticipated study revisions
- Competing studies for the same population
- Study timelines for logistic concerns

6. Discuss protocol review comments with the Sponsor and research team.

7. If PI and/or department rejects the study, promptly relay this information to the Sponsor. Include reasons for rejection and a summary of study topics that meet your criteria for acceptance in order to keep the communications open.

8. If it is determined that the study protocol meets the above mentioned criteria and the PI and CTO are in agreement to proceed with the study, the PI or study team will notify the sponsor/CRO.

Additional Resources

RELATED FORMS:
Initial Study Feasibility Assessment

RELATED POLICIES:
N/A

History
N/A

Next Review Date
August 2023

Responsible Party
Director, Clinical Trials Office