EFFECTIVE DATE: August 2023

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.

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.

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.

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

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.

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:

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.