CT-309 CHANGE OF PRINCIPAL INVESTIGATOR

EFFECTIVE DATE: March 2024

Purpose

The Principal Investigator (PI) is the individual with primary responsibility for carrying out the sponsored project. The PI is legally accountable to the University of South Alabama (USA) and to the sponsoring agency for the proper execution of the project. Additionally, the PI is responsible for protecting the rights, safety, and welfare of the subjects enrolled on the study.

This policy and procedure provides the standards required to pass the above stated responsibilities to a new PI while maintaining the study's integrity and the subjects' safety.

Scope

This policy and procedure applies to all Principal Investigators performing research with the University of South Alabama's Clinical Trials Office. This policy also serves to provide guidance to Clinical Trials Office staff who are delegated to submit regulatory communications and submissions on behalf of the Principal Investigator.

Policy

Any change in status or effort of the Principal Investigator (PI) of a research study is required to be in compliance with the sponsor's guidelines and the University of South Alabama's policies. A substitute PI must be named in the event that a PI is absent from regular duty, including leaves of absence, for 90 days or more.

The departing PI has the responsibility for initiating notification of any such change. If the PI is unable to initiate such notification, the department Chair or designee has the responsibility to notify all applicable parties.

The new PI should meet the standards listed in the Sponsored Projects Administration's Principal Investigator Policy as well as CT102 Qualified Investigators and Research Staff. The new PI must be

approved by the department's Chair prior to initiating the below procedures. The new PI should be approved by the Sponsor as applicable.

Procedure

All of the below procedures should be completed to the departing PI's last day (if applicable).

Investigator's Qualifications and Agreements

1. The new investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).
2. The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
3. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
4. Notify the sponsor of the intent to change PIs. The new PI should be approved by the sponsor as applicable.
5. The appropriate departments managing the trial contracts should be notified to initiate the process of changing the contract to the new PI.

Adequate Resources

1. The new investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
2. The new investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
3. The new investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
4. The new investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

Medcal Care of Trial Subjects

March 2027

Responsible Party
Director, Clinical Trials Office