CT-202 REGULATORY REPORTING REQUIREMENTS

EFFECTIVE DATE: May 2023

Purpose

To describe the reporting requirements of various events as set forth by federal regulations and Good Clinical Practice (GCP).

Scope

This policy applies to all study documents and events requiring submission to an Institutional Review Board (IRB) or study sponsor. Events include Adverse Events (AEs), protocol deviations, protocol violations, continuing review, participant complaints, and safety concerns. Documents may include recruitment material, protocol and amendments, Investigator Brochure and amendments, Informed Consent and amendments.
All research performed through the Clinical Trials Office at the University of South Alabama are subject to this policy and procedure.

Definitions

Adverse Event: Any untoward medical occurrence in a clinical investigation subject.

Deviation: Any noncompliance with the protocol, good clinical practices, regulatory or institutional requirements.

IRB of Record: A reviewing IRB that assumes IRB responsibilities as outlined in federal regulations and is designated to do so through an approved Federalwide Assurance on file with the federal Office for Human Research Protections. For this policy and procedure, unless otherwise specified, all references to IRB will refer to the IRB of record.

Serious Adverse Event (SAE): An adverse event that results in any of the following outcomes:

a. death;

b. a life-threatening adverse experience;

c. inpatient hospitalization or prolongation of existing hospitalization;

d. a persistent or significant disability such to disrupt a person's ability to conduct normal life functions;

5. Report significant complaints from participants or others.

    5.1. Report to the IRB those complaints that involve potential risks to participants or others, or that may change the risk/benefit ratio.

    5.2. Report complaints concerning subject rights submitted by subjects or concerned parties, family members, or study personnel.

6. Report proposed modifications to approved protocol or ICF.

    6.1. Protocol or ICF modifications should be submitted to the IRB after the Sponsor has agreed to the change(s).

    6.2. IRB must approve changes before implementation, except to immediately protect the health of a subject. Emergency changes to the protocol to protect the health of the subject must

RELATED FORMS: