UNIVERSITY OF SOUTH ALABAMA

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;

e. a congenital anomaly/birth defect;

f. certain medical events that may not result in death, be life-threatening, or require hospitalization, may also be considered a serious adverse event when appropriate medical or surgical intervention is necessary to prevent one of the outcomes listed above.

Unanticipated Problem: An event not previously identified involving risk to the participant or others.

Policy

The University of South Alabama's Institutional Review Board (IRB) must be fully informed and approve of all research at the University of South Alabama and USA Health regardless of the IRB of record. No study procedures may begin until the IRB of record provides approval in writing. Any changes to the study plan or documents must also receive written IRB approval from the IRB of record prior to implementation. Any deviations from the study plan must be promptly reported to the IRB of record using the procedure outlined below. Adverse events, safety concerns, and participant complaints must be submitted to and receive IRB acknowledgement per the below guidelines and the corresponding IRB SOPs.

Additional reporting requirements may be needed for studies using an external IRB. Site should refer to USA IRB policies for studies where USA IRB is not the IRB of record. Policies are outlined in the additional resources section below.

Procedures

1. Acknowledgement must first be received by USA IRB for studies requesting the use of an external IRB.

2. Prior to the initiation of study procedures, submit study documents to the IRB for review.

    2.1. Documents include the protocol, ICF, Investigator's Brochure (IB), recruitment material, Data Safety Monitoring Plan, etc.

    2.2. No research related activities may start until the IRB provides approval in writing.

3. Notify the IRB of reportable events using the current submission/reporting process, according to the policies of the IRB of record.

    3.1. Reportable events/actions may include: adverse events, unanticipated problems (UPs), safety reports, protocol deviations, breaches of confidentiality or others.

    3.2. Follow-up information for events should be reported as available.

4. Serious Adverse Events (SAE) must be reported to the Sponsor within 24 hours of the study team becoming aware of the event. SAEs and Adverse Events should be reported to the IRB per their reporting policies.

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 be reported as soon as possible and no more than five working days after the occurrence.

7. Periodic reporting/renewal submission to the IRB must be done at least annually.

    7.1. Actual renewal period will be determined by the IRB during the initial review process.

    7.2. The study is not allowed to continue if a renewal is not obtained.

    7.3. Periodic/renewal reports should be submitted soon after the initial expiration reminder from the IRB. This practice will avoid lapses in review due to unforeseen circumstances (i.e. lack of quorum).

    7.4. Changes or updates to critical research staff should be made no later than the time of the renewal.

8. Deviations from the protocol should be reported to the Sponsor and IRB according to their individual guidelines.

9. A deviation from the protocol should not be willfully executed without prior approval from the IRB and Sponsor unless it is to immediately protect the health of a subject. Protocol deviations should be reported to the IRB per their reporting guidelines.

10. Material used in the recruitment of research subjects must be approved by the IRB prior to implementation. IRB approval is not needed for recruitment material that potential subjects *will not* encounter such as a Doctor-to-Doctor letter.

11. Refer to the governing IRB's SOPs or policies and procedures for additional information. If the Clinical Trials SOP and the IRB's SOP conflict, the IRB's SOP will prevail.

Additional Resources

RELATED FORMS:

- **REGULATORY BINDER CHECKLIST AND ORGANIZATIONAL FORMAT**

RELATED POLICIES:

- **CT 304 COMPLIANCE WITH THE PROTOCOL**
- **USA IRB POLICY 1101: WCG IRB**
- **USA IRB POLICY 1102: NATIONAL CANCER INSTITUTE: CENTRAL IRB**
- **USA IRB POLICY 1103: EXTERNAL INSTITUTIONAL REVIEW BOARDS**
- **USA IRB POLICY 1104: SINGLE IRB POLICY FOR MULTI-SITE FEDERALLY FUNDED RESEARCH**
- **USA IRB POLICY 1105: IRB PROCEDURES: RELYING ON A SINGLE IRB FOR MULTI-SITE FEDERALLY FUNDED RESEARCH**

History

N/A

Next Review Date

January 2026

Responsible Party

Director, Clinical Trials Office