UNIVERSITY OF SOUTH ALABAMA

CT-106 EMERGENCY PREPARATION AND CONTINUITY PLAN

EFFECTIVE DATE: May 2023

Purpose

The purpose of this policy is to help guide Principal Investigators and Clinical Research Staff in the event of an emergency such as a natural disaster or otherwise unforeseen event. Staff and study participant health and safety is of paramount importance. Adherence to the study protocol to the extent that protects the study participant's welfare and data integrity is crucial.

Scope

This procedure applies to all Clinical Trials Office staff and research performed through the Clinical Trials Office.

Definitions

N/A

Policy

The objectives for PIs and Clinical Research Staff must include:

- A plan to continue FDA-regulated studies where investigational drugs or devices are involved.
- A capability of communicating with staff, study participants, and regulatory authorities.
- Procedures for access to investigational drugs and devices during a disaster, especially if an evacuation has disrupted normal research operations.
- Written documentation of the continuity plan for each clinical trial or category of clinical trial.

Procedures

The following preparations should be in place prior to any impending emergency event:

- Clinical Trials Director will maintain an up-to-date list of research staff contact information. Contact information should be kept online in an area accessible off-site and include, at

minimum: Name, cell phone number, office phone number, emergency contact name and phone number.

- Clinical Trials Director will maintain an up-to-date list of ancillary departments involved in active clinical trials. List should include: Department name, contact names, titles, phone numbers, email addresses

- Update information on funding organization/program officer contact info for funded research programs

- Primary coordinators will maintain an up-to-date list of research subjects with all contact information. This information should be organized by study and easily accessible by all research staff.

- The primary coordinator for each study will provide research participants with a contact number of the study personnel.

- Keep a copy of the research contact list and study-staff in a secured off-site location.

- Establish a process to un-blind studies in the case of a disaster and to provide investigational drugs for treatment purposes

- Ensure clear procedures exist to secure and access investigational drugs and devices during a disaster.

- Establish partnerships with other academic institutions so collaborative emergency sites are available.

- Ensure all research staff have access to electronic research files from a remote location.

- Ensure all paper research records are kept in a safe and dry location, away from potential water damage.

- Clinical Trials Director will ensure all research staff is familiar with the University/Clinical Site's Emergency Preparedness Plan

The following preparations should be implemented upon notification of impending emergency event:

- Contact research participants currently on active treatment or with upcoming appointments and provide direction regarding any medications or study visits.

- Confirm contact information with all study participants in active treatment or with upcoming appointments.

- Clinical Trials Director will update the contact list for all research study-staff and distribute to each member.

- Complete as much study activity as possible in advance of the event, within the constraints of the protocol.
- Follow the pre-arranged plan for securing study samples, investigational product and research data (ship specimens to the Sponsor or relocate to a more secure alternate location).
- Notify study sponsor/CRO of any known upcoming emergencies that may affect study protocol or procedures. Anticipated deviations that may occur as a result of the emergency should be communicated with the sponsor and all study staff.

Business Continuity:

During the emergency event:

- Ensure the safety of clinical trial staff and participants.
- Follow the lead of the clinical sites in moving participants to other areas.
- Monitor investigational product electronic temperature monitoring system for temperature excursions

Following the emergency event:

- Confirm the safety of clinical trial staff and participants.
- Verify the stability of the study participant's samples, study drug, data, etc. and if necessary, arrange for their return.
- Document any damages and notify the Clinical Trials Director, PI, study sponsor.
- Document any protocol deviations that occurred as a result of the emergency. Immediately notify the PI, Clinical Trials Director, study sponsor/CRO, and IRB.
- Resume the protocol timeline as soon as practical.

Additional Resources

RELATED POLICIES:

History

N/A

Next Review Date

January 2026

Responsible Party
Director, Clinical Trials Office