Investigator Study-Specific Emergency Disaster Checklist

The purpose of this checklist is to provide investigators with general guidance and considerations when developing study-specific emergency disaster plans to help protect the continuity of research during an emergency.

General

- ☐ Emergency disaster plan is available for each project where interruption of research activities due to an emergency (natural disaster, pandemic, technology outage, etc) could increase risks to participants.
- ☐ Emergency disaster plans are reviewed annually by study team.

Communication and Reporting

- ☐ Emergency plan includes steps to maintain contact with research facilities/resources (IRB, IDS, Sponsors, Monitors, FDA, etc) critical to the continuity of human subject research during an emergency.
    - Contact information should be accessible during remote operations and in situations where university network systems may not be accessible.
- ☐ Emergency plan includes steps to maintain contact with research participants during an emergency to communicate any required study-specific modifications.
    - Contact information should be maintained for all active participants on FDA regulated studies, or studies where increased risk could occur if activities abruptly stopped during an emergency.
    - Contact information should be accessible during remote operations and in situations where university network systems may not be accessible.
- ☐ Emergency plan includes steps to maintain contact with departmental leadership during an emergency.
- ☐ Emergency plan includes steps to continue necessary reporting to the IRB (Noncompliance, unanticipated problems, deaths, emergency use, etc).

Modifications

- ☐ Emergency plan includes process for implementing any necessary protocol modifications if MU Health Care or University of Missouri campus access becomes restricted.
    - Plan identifies research activities that can be completed remotely.
    - Plan identifies research activities that can be modified, delayed, skipped without increasing participant risk.
    - For FDA-regulated studies

- Plan includes contact information for consultation with IRB, FDA prior to any modifications when feasible.
- Plan identifies alternative delivery methods for products that can be sent to participants for self-administration.
- Plan identifies if alternative sites/resources (home nursing, off-site clinics, etc) can be utilized for products requiring administration in a healthcare setting.

Research Records and Study Documentation

- ☐ Emergency plan includes process for study team to maintain a current copy of the most recently approved IRB application including all approved uploaded documents.
    - Copies (electronic or paper) should be accessible during remote operations and in situations where university network systems may not be accessible.
- ☐ Emergency plan includes steps for secure collection/storage of data and biospecimens during an emergency.
    - Plan should include steps for collection of data when study activities transition to remote completion and in situations where university network systems may not be accessible. This plan should maintain the required level of security to protect any identifiable participant data.
    - Plan should include steps for documentation of any protocol deviations, study changes implemented during an emergency.
    - If study includes collection and storage of biospecimens, plan should include steps for ensuring biospecimens are collected timely and following approved collection methodology. Storage of biospecimens should include plan to ensure viability of specimens regardless of emergency situation for any biospecimen being utilized for participant safety.
- ☐ Emergency plan includes process for study team to maintain a current copy of the University of Missouri HRPP Emergency Preparedness and Response Plan.
    - Copies (electronic or paper) should be accessible during remote operations and in situations where university network systems may not be accessible.
        - https://docs.research.missouri.edu/human_subjects/SOP_Emergency_Preparedness.pdf

Recovery

- ☐ Emergency plan includes sequential steps for returning to normal activities once emergency has resolved.

- Plan should include process for reporting deviations, updating research records, contacting participants, resuming recruitment, etc.