UF UNIVERSITY of FLORIDA

Guideline: Emergency Preparedness and Response

The purpose of this document is to establish the steps for responding to emergency situations associated with natural disasters, man-made disasters or public health crises that require alterations to standard operations of the HRPP.

Introduction

The processes outlined here will begin when an emergency or disaster situation is imminent or when such a situation has occurred that impacts the HRPP operations. HRPP leadership will determine when to enact emergency response measures based on state, local, federal and University of Florida guidance.
The Director of Research Operations and Services or designee is responsible for carrying out these procedures. The process ends when HRPP leadership determines that impact to the HRPP is over, and standard operations can resume.

Overall plan

The UF Comprehensive Emergency management Plan (CEMP) will be followed for all disaster situations and emergency response planning falling outside of what is specific and limited to the HRPP.
If an emergency or disaster situation has occurred or is imminent, first determine the response based on the nature of the event. Then assess the risk and potential impact to the HRPP operations.

The Director of Research Operations and Services will contact the Institutional Official (IO) and refer to the UF CEMP for an existing plan already in place to address the current or anticipated event, proceed with any institution wide plans and determine if communication with the research community is necessary to alert them to the activation of the HRPP emergency response plan.

IRB Meetings: If the emergency or disaster situation will potentially prevent IRB meetings form occurring, determine if the meetings need to be rescheduled or canceled. Be certain to identify currently approved human research that may expire before the next IRB meeting. If research will expire, the IRB Chair or designee will contact the investigator to determine if any subjects need to continue in the expired research for safety purposes and to determine which assessments and/or procedures must continue and why.

IRB staff protocol processing and review: If staff will be unable to complete their protocol processing and review, or if capacity is limited, the Associate Director of IRBs or designee will work with staff to prioritize reviews. If IRB operations are limited, the Director of Research Operations and Services will work with the IO to notify the research community of the IRB Office's limited capacity to process and review submissions.

myIRB and electronic records: If electronic records and/or the myIRB system is unavailable, consult with UF IT to determine alternative procedures to access and back-up data.

Flexibility in IRB Review: The IO is responsible for determining any action to take during the emergency to continue research activities. Assess whether the emergency or disaster situation could necessitate additional flexibility in IRB review, where appropriate. Flexibility in IRB review may only be considered for minimal risk research that is not federally funded or supported.

Actions that may be considered to continue research during an emergency or disaster situation include and are not limited to implementing any flexibility in IRB review, postponing new study approvals, suspending current research, continuing research via alternative methods and reliance of external IRBs for oversight. In consultation with the IRB Chairs and HRPP leadership, the IO will define any actions that can be taken during the emergency or disaster situation to continue research.

Consideration to the following will be given when determining actions that might be taken during the emergency or disaster situation to continue research activities: risk of research interactions and interventions, how the risks could be managed and the likelihood of direct benefit to participants.

The IO is responsible for evaluating the emergency response plan at least annually in accordance with policies HRP-141 Annual Evaluation of the HRPP and HRP-010 Human Research Protection Program.

General guidelines and considerations when developing study-specific mitigation plans to ensure the ongoing safety of research subjects.

Safety monitoring: To ensure the safety of research participants, assessments may need to continue during the emergency or disaster situation. Investigators need to consider whether they can conduct the study per the protocol as written or if alternative methods for safety assessments need to be considered to eliminate apparent immediate hazard to participants (45 CFR 46.108).

Assess whether the emergency or disaster situation could impact some or all investigators' ability to conduct Human Research.

Modifications to Minimize Risk might include conducting visits virtually or by phone, completing imaging or labs locally, changing the timing and scope of visits to account for essential versus nonessential study procedures. Consider whether the emergency or disaster situation could impact study staffing or obtaining the supplies needed to conduct study visits.

Except when modifications are made to eliminate apparent immediate hazard to participants any changes to research that deviate from the approved protocol **must be approved by the IRB** prior to being implemented. Emergency deviations made to eliminate apparent immediate hazard to participants must be submitted to the IRB within 5 days of the occurrence or learning of the occurrence.

Research that is externally sponsored, should include guidance from the sponsor when developing a protocol-specific risk mitigation plan for the research.

Modification to FDA regulated research may require consultation with the sponsor, IDS, and applicable FDA review division.

Documentation in the research record should include any modifications necessitated by the emergency or disaster situation. Such as changes in study conduct, duration of the changes, which study participants were impacted and how.

Consider what information needs to be communicated to study participants. Identify who will notify participants, how and when they will be notified of any relevant study modifications.

Communication during the emergency or disaster situation

Communication will occur through the standard methods, such as email and web-based platforms, if available. If these routes of communication are unavailable, consult the UF CEMP and/or contact UF IT for institutional plans in place to address communications.

Specific communication and direction during an emergency will be distributed based roles and responsibilities within the HRPP. When the emergency/disaster no longer limits HRPP activities, HRPP leadership will work with the IO to notify the research community of the return to normal operations.

References:

Comprehensive Emergency Management Plan, University of Florida 07/31/2023
21 CFR §56.108
HRP-141 Annual Evaluation of the HRPP
HRP-010 Human Research Protection Program