

SOP: Emergency Preparedness Plan for the HRPP				
Approved By	Effective Date	Revised Date	Review Date	Archived Date
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PURPOSE:

This SOP establishes written procedures for initiating a response to an emergency impacting the UAMS Human Research Protection Program (HRPP) or HRPP operations.

An emergency may include but is not limited to natural disasters, weather events, man-made disasters, and public health crises.

This SOP establishes HRPP-specific emergency planning and is intended to supplement, not replace, emergency response planning by Institutional leadership and/or Institution-wide response measures. HRPP-specific emergency response planning and measures are limited only to those functions of the HRPP not otherwise covered by institution-level plans.

This SOP is invoked once the Organizational Official has indicated an emergency has occurred or preparations are needed for an imminent emergency, and human research at UAMS, including the HRPP or HRPP operations, is or is likely to be adversely impacted.

RESPONSIBILITY:

Implementation of the Plan - The Organizational Official and/or designee; the Institutional Review Board (IRB) Director, Chair, Co-Chairs; leaders of other HRPP components, including the leaders of the Cancer Institute and the Translational Research Institute and/or their designee, and, as may be indicated, other organizational leadership are responsible for carrying out the procedures described in this SOP.

SCOPE:

Throughout this document "organization" refers to the University of Arkansas for Medical Sciences.

PROCEDURE:

1. Assess the Nature of the Risk and the Potential Impact to the HRPP

Once an emergency or imminent emergency is identified, determine the response based on the nature of the event. UAMS leadership will contact the Organizational Office or appropriate Institutional personnel to determine whether there are Institutional plans already in place to address the event. Refer to the UAMS All Hazards Emergency Operations Plan. If these plans are activated, proceed in accordance with

those plans and determine whether communication with the research community is necessary to alert them to the activation of the emergency preparedness plan.

2. Assess Whether the Emergency may Impact HRPP Operations

a. IRB Meetings

If the emergency may prevent one or more IRB meetings from occurring, determine whether to cancel or reschedule the meetings, being certain to identify currently approved human research which may expire prior to IRB review. If research will expire, follow [IRB Policy 7.6 Continuing Review](#) regarding lapses in continuing review.

Because the IRB meets remotely, every attempt will be made to continue IRB meetings to the extent possible.

b. IRB Staff Protocol Processing and Review

If staff will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, IRB leadership will work with the staff to prioritize reviews. If research will expire, follow [IRB Policy 7.6 Continuing Review](#) regarding lapses in continuing review.

Because the IRB office staff, chair, and reviewers have the capacity to work remotely, every attempt will be made to continue/restore regular IRB office operations as quickly as possible.

c. Data and Records

If electronic records are unavailable, consult with UAMS Technology (IT) support to implement alternative procedures to access backup data.

3. Assess whether the emergency may impact investigators' ability to conduct research.

In-person interactions with research subjects: If studies involve in-person interactions with research subjects, organizational leadership will determine whether the studies may be conducted as written while adhering to emergency mitigation strategies.

a. Sponsored Research

When studies have an external sponsor, ensure coordination with each sponsor to confirm mitigations plans.

b. Clinical Care and/or Research Facility Considerations

If the emergency impacts clinical care standards which may in turn impact research, clarify what does and does not require IRB review. For example, in the case of a public health crisis, screening procedures implemented by the health care system where a clinical trial is being conducted would not require IRB review/approval of the screening procedures. Conducting research procedures at an alternate clinical care location may require prospective IRB approval. Patient safety will take priority above all other considerations;

measures implemented immediately to ensure patient safety may be reported retrospectively. Emergency response plans must be considered for each existing research location.

c. Safety Monitoring

If trial participants are unable to come to the investigational site for protocol-specified visits, alternative methods for safety assessments must be considered. This may include utilizing phone contact, virtual visits, and/or alternative locations for assessment (including local labs or imaging centers) to assure the safety of trial participants.

4. Consider Necessary Actions to Address the impact of the Emergency

UAMS Leadership, will determine the actions to take during the emergency to minimize research disruptions. Possible actions include, but may not be limited to, the below.

a. Postponing New Study Implementation

Consider delaying review and/or startup of new protocols that are non-interventional in nature, present no direct benefit to participants, and do not pertain to the current emergency.

b. Suspending Enrollment/Recruitment on Open Studies

The institution may need to identify studies for which recruitment and/or enrollment should be suspended, but ongoing study interventions may continue.

c. Continuing Studies via Alternate Mechanisms

When possible, implement online or remote strategies for research procedures such as recruitment, consent, data collection, debriefing, and follow-up. Identify any additional research activities that can be completed via telephone, video conference, or via online mechanisms. If possible, alter the timing of visits and procedures.

d. Relying on Another Organization to Provide IRB Oversight

Make arrangements (when possible, in advance of an emergency) as necessary to rely upon other organizations for IRB review. Identify the external IRBs and ensure reliance agreements are in place in accordance with [IRB Policy 2.3 Use of Single/Central IRBs.](#)

e. Employing Strategies to Exercise Flexibility in Oversight

When studies are not federally regulated, organizations may employ different but equivalent procedures in terms of protecting the rights and welfare of research participants. For example, for non-federally funded or supported research, the IRB may consider extending continuing review dates during the emergency, and/or allowing minor changes in research to be reported to the IRB at the time of continuing review versus in advance of the change. Further, for most minimal risk research regardless of funding, the IRB may consider

more widespread use of waivers of documentation of consent. This strategy may be considered particularly for notifying participants of changes to consent documents.

5. Triage the Research that will be Subject to the Emergency Mitigation Strategies

The organization will consider the types of research that may continue and the types of research that may need to be temporarily postponed. This consideration may include:

- a. Studies which present a likelihood of direct benefit to participants (or conversely, studies which include study interventions which may be harmful to subjects if discontinued) should not be postponed, to the extent possible.
- b. Research involving direct interactions or interventions but can continue those interventions via alternate mechanisms (such as remote visits) may continue.
- c. Studies which may have an adverse impact on resources required to address the emergency must be postponed, if possible.

6. Develop Education, Training, and Communications on Expectations During an Emergency

Targeted communications and education/training must be developed and distributed based on roles/responsibilities within the HRPP. In particular, researchers and research staff, IRB Chairs and IRB members, IRB Staff, and departmental administrators may each have differing needs regarding effectively responding to emergency mitigation strategies.

The organization will communicate research-related measures implemented in the event of an emergency via standard communication routes, such as email and web-based platforms, if available. If the standard routes are not available, consult the institutional plans in place to address communications. Ensure the communications include instructions and expectations for impacted personnel.

7. Prepare and File Necessary Plans with the Appropriate UAMS Institutional Office

File the HRPP emergency preparedness plan with the Emergency Management Department.

At least annually, review the emergency preparedness plan and update as necessary. Following the review, communicate the plan to the research community, including Human Research Protection Program staff.

REFERENCES:

- AAHRPP Element I.1.H
- AAHRPP Tip Sheet - Emergency Preparedness and Response
- UAMS All Hazards Emergency Operations Plan
- IT Research SOP-003 System Backup Plan and Disaster Recovery
- UAMS Administrative Guide Policy 10.1.2 Continuity of Operations