1 PURPOSE

This SOP establishes written procedures for initiating a response to an emergency impacting the UNC 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 Institutional Official (IO) has indicated an emergency has occurred or preparations are needed for an imminent emergency, and human research at UNC, including the HRPP or HRPP operations, is or is likely to be adversely impacted.

2 RESPONSIBILITY

Implementation of the Emergency Plan - The IO and designee; the Institutional Review Board (IRB) Chairs, Co-Chairs, and Vice-Chairs; Office of Human Research Ethics (OHRE) leadership; and the Safety/Compliance team are responsible for carrying out the procedures described in this SOP.

Periodic Evaluation of the Emergency Plan – The OHRE Director is responsible for evaluating the emergency preparedness plan and making changes, when appropriate. This evaluation shall occur at least annually.

Periodic Review of the Emergency Plan Educational Materials – The OHRE Director is responsible for ensuring the educational materials are reviewed and updated as necessary, based on the outcome of the periodic evaluation of the emergency preparedness plan.

3 PROCEDURES

3.1 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. OHRE leadership shall contact the IO or appropriate Institutional personnel to determine whether there are Institutional plans already in place to address the event. Refer to the Mission Continuity Plan on file with the Office of Emergency Management and Planning utilizing the Tar Heel Mission Ready software system. 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.
3.2 Assess whether the emergency may impact HRPP operations

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 UNC HRPP SOP 701 IRB Review Process regarding lapses in continuing review.

OHRE Staff protocol processing and review: If staff will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, OHRE leadership shall work with the staff to prioritize reviews. If research will expire, follow UNC HRPP SOP 701 IRB Review Process regarding lapses in continuing review.

Data and records: If electronic records are unavailable, consult with UNC Information Technology (IT) support to implement alternative procedures to access backup data.

3.3 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, determine whether the studies may be conducted as written while adhering to emergency mitigation strategies.

Sponsored research: When studies have an external sponsor, ensure coordination with each sponsor to confirm mitigation plans.

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 healthcare 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. Emergency response plans must be considered for each existing research location.

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, alternative locations for assessment (including local labs or imaging centers) to assure the safety of trial participants.

3.4 Consider necessary actions to address the impact of the emergency

OHRE Leadership, in consultation with the IO and IRB Chairs, as needed, shall define the actions to take during the emergency to avoid stopping all research activities.

Postpone new study implementation: Consider not accepting submissions of new protocols for IRB review for research which is non-interventional in nature, or which presents no direct benefit to participants.

Suspending existing research: The IRB may need to identify studies for which recruitment and/or enrollment should be suspended, but ongoing study interventions may continue.

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.

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 UNC HRPP SOP 901
Multicenter Research and Reliance Process.

Employ 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-federal 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.

3.5 Triage the research that will be subject to the emergency mitigation strategies

Consider the types of research that may continue and the types of research that may need to be temporarily postponed. This consideration may include:

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) shall not be postponed, to the extent possible.

Research involving direct interactions or interventions but can continue those interventions via alternate mechanisms (such as remote visits) may continue.

Studies which may have an adverse impact on resources required to address the emergency shall be postponed, if possible.

3.6 Develop education, training, and communications on expectations during an emergency

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

Communications shall occur 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.

3.7 Prepare and file necessary plans with the appropriate UNC office

File a Mission Continuity Plan with the Office of Emergency Management and Planning utilizing the Tar Heel Mission Ready software system.

At least annually, review the Mission Continuity Plan and update as necessary. Following the review, communicate the plan to the research community, including OHRE staff.

4 REFERENCES

AAHRPP Element I.1.H

AAHRPP Tip Sheet – Emergency Preparedness and Response

University of North Carolina Chapel Hill Policy on Continuity Planning/Tar Heel Mission Ready Planning