706 Human Subjects Research & Emergency Management

Standard Operating Procedure 706: Human Subjects Research & Emergency Management

I. Purpose

Natural or man-made disasters and other emergencies can affect the Utah State University Human Research Protection Program (HRPP) or HRPP operations and pose an actual or potential threat to public health and safety. The HRPP Emergency Response Plan establishes the policy and procedures for initiating a response to an emergency impacting the HRPP or HRPP operations.

II. Scope

This plan supplements, and is not intended to replace, University-wide emergency response planning and measures.

Foreseeable emergencies include:

- Public health emergencies (e.g., Infectious Disease Outbreaks)
- Extreme weather events
- Human-caused events (e.g., Cyber-threats and Chemical, biological, radiologic, or nuclear threats; active shooters)
- Natural disasters

Areas of the HRPP that may be impacted include:

- HRPP Staff and IRB Membership ability to communicate about and provide review and oversight of human research
- Researcher and research participant ability to complete study visits
- HRPP/IRB and researcher access to program and project records

III. Emergency Management & Human Subjects Research

The HRP Executive Director and the Institutional Official (IO) or Designee are responsible for annual evaluation of the emergency management plan. The plan is evaluated to ensure it is appropriate to the size and complexity of the HRPP, during the time when the Office of Research annually reviews and updates its Departmental Emergency Management plans.

The Human Research Protections Office provides access to this plan to all members of the organization through the Utah State University Human Research Protections Standard Operating Procedure Library.

The HRPP staff provide education about this emergency response plan for IRB members, staff, researchers, and other members of the HRPP via the Investigator Handbook, available University communication channels such as email notifications during emergencies, websites, presentations to departments and administrative units, and meetings with individuals, committees, or groups within departments or units when requested.
The HRP Executive 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.

When an emergency occurs, the HRPP Director, in consultation with the IRB leaders (i.e., IRB Chair, Vice-chair) and the IO or Designee are responsible for implementing the procedures in this plan, beginning with an assessment of the nature of the risk and the potential impact on the HRPP.

IV. Onset of an Emergency

When an emergency arises, after the departmental emergency management plan has been attended to, the HRP Executive Director in consultation with Institutional Official (IO) or Designee assess whether the emergency may impact HRPP operations and/or infrastructure (e.g., submission portal, damage to offices, servers destroyed with e-data). In so doing, they consider the following:

- IRB Meetings: If an emergency may prevent one or more IRB meetings from occurring, determine whether to cancel or reschedule the meetings, being certain to identify current approved human research for which approval may expire prior to IRB review.
- HRPP Staff submission processing and review: If staff will be unable to process submissions and conduct reviews, or if capacity will be limited, prioritize areas of responsibility and cancel or temporarily halt tasks that will not adversely impact participants.
- Data and records: If electronic records and systems are unavailable, consult with the Office of Research, the Director of Research Administration Systems, and, if necessary, Utah State University Information Technology to implement alternative procedures to access backup data.
- Assess whether the emergency may impact investigators' ability to conduct research (e.g., damage to infrastructure, security of facilities). Considerations include:
    - In-person interactions with participants: If research projects 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 projects have an external sponsor, inform investigators of their responsibility to coordinate with each sponsor to confirm mitigation plans.
    - Clinical care and/or facility considerations: If the emergency impacts clinical care standards which may in turn impact research, clarify what does and does not require IRB review and instruct investigators to communicate with the research sites to obtain their emergency plans or policies.
    - Safety monitoring: If trial participants are unable to come to the research site for study visits, alternative methods for safety assessments must be considered. This may include utilizing phone contact, virtual visits, or alternative locations for visits.

They must also consider necessary actions to address the impact of the emergency. Options include:

- Postpone new study implementation: Delay acceptance of new study submissions for research that is non-interventional in nature, or which presents no timely direct benefits to participants.
- Suspend enrollment for approved research: The IRB may need to identify studies for which recruitment and/or enrollment should be suspended, but ongoing study interventions may continue.
- Continue 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.
- Expand review flexibility: For studies that are not regulated (i.e., are not federally sponsored), employ existing flexibility policies broadly and consistently to reduce administrative burden while ensuring equivalent protection of participants. For example, employ widespread use of waivers of documentation of consent and institutional exempt categories.
- Reliance mechanisms: Utilize existing reliance agreements and close working relationships, or seek additional reliance agreements with other organizations to shift a portion or all of the IRB reviews to external IRBs, temporarily or permanently.
- If the transfer to an external IRB is permanent: Identify studies for which IRB oversight is being transferred; ensure availability and retention of pertinent records; establish an effective date for transfer of oversight, including

records for the projects; and notify key parties after the receiving IRB reviews the studies and accepts oversight responsibility via an existing or newly executed reliance agreement or other reliance method.

- If the transfer to an external IRB is temporary (e.g., a natural disaster temporarily disrupts normal functioning), additional review by the IRB may not be necessary when oversight is transferred back to the Utah State University IRB.
- Triage the research that will be subject to emergency mitigation strategies. Identify the types of research that may continue and the types of research that may need to be temporarily halted. Consider the following:
  - Studies that present a likelihood of direct benefit to participants (or conversely, studies that include study interventions which may be harmful to subjects if discontinued) should not be delayed or halted, to the extent possible.
  - Research involving direct interactions or interventions that can be continued via implementation of alternate methods (for example, remote or virtual visits) may continue.
  - Studies that may have an adverse impact on resources needed to provide clinical care or to address the emergency should be halted or delayed.
- In instances when halting or delaying procedures may endanger participants but the investigator or IRB is not able to conduct activities, it may be appropriate to attempt to find a qualified external investigator and IRB to take over the conduct and oversight of the study in order to permit the study to continue.
- Assess whether new or additional educational materials are needed, including but not limited to the following:
  - Decision tree or guidance for investigators to self-determination if activities should be halted, delayed, or continued according to HRPP triage procedures and, if they can be continued, whether or not a modification submission is required.
  - Worksheets to help investigators assess their ongoing projects and proposed new activities to determine appropriate methods to reduce risks.
  - Guidance on alternative methods that may be appropriate for different types of studies.
  - Guidance on how to seek external IRB review.