

Emergency Preparedness Plan for the Human Research Protection Program (“Plan”)

Purpose

This Plan establishes written procedures for initiating a response to an emergency impacting the Human Research Protection Program (HRPP) or HRPP operations at Stony Brook University. An emergency may include but is not limited to natural disasters, weather events, man-made disasters, and public health crises.

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

This Plan 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 Stony Brook University, including the HRPP or HRPP operations, is or is likely to be adversely impacted.

Responsibility

Implementation of the Plan - The Institutional Official; the Institutional Review Board (IRB) Chairs, Alternate Chairs; Vice President for Research and Innovation; and the Office of Emergency Management are responsible for carrying out the procedures described in this Plan.

Periodic Evaluation of the Emergency Plan – The Assistant Vice President for Research Compliance 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 Assistant Vice President for Research Compliance 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.

Emergency Contacts

- Police/Fire/Medical: 911 or 631-632-3333
- Urgent Facility Issues: 631-632-6400
- Building Manager for Melville Library: John Madonia 631-632-9795

Emergency Procedures

Once an emergency or imminent emergency is identified, determine the response based on the nature of the event. The Vice President for Research and Innovation shall contact the IO or appropriate Institutional personnel to determine whether there are Institutional plans already in place to address the event. This policy refers to the procedures on file with the Office of Emergency Management utilizing the SBAAlert system.

If these procedures are activated, proceed in accordance with those procedures and determine whether communication with the research community is necessary to alert them to the activation of the emergency preparedness plan.

The IO will conduct the following assessment:

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 [\(3.12.5\)](#) “What Happens if there is a Lapse in Continuing Review?” regarding lapses in continuing review.

Stony Brook University staff protocol processing and review: If staff will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, the Office of Research Compliance leadership will work with the staff to prioritize reviews. If research will lapse, follow [\(3.12.5\)](#) “What Happens if there is a Lapse in Continuing Review?” regarding lapses in continuing review.

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

Assess whether the emergency may impact an 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 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. 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.

Consider necessary actions to address the impact of the emergency

The Vice President for Research and Innovation, in consultation with the IO and IRB Chairs, as needed, will 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 enrollment of 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 (in advance of an emergency) to rely upon other organizations for IRB review. Identify the external IRBs and ensure reliance agreements are in place.

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 minimal risk research regardless of funding, the IRB may consider more widespread use of waivers of documentation of consent.

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 that 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 should be postponed, if possible.

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

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

Communication will occur via standard communication routes, such as email and web-based platforms, if available. If the standard routes are not available, a consultation will occur with the institutional plans in order to address communication. The Office of Research Compliance staff will ensure the communication includes instructions and expectations for impacted personnel.

Prepare and file necessary plans with the appropriate Stony Brook University office:

File an emergency preparedness plan with the Office of Emergency Management. 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

Stony Brook University Emergency Management Procedures