

## Tip Sheet 29: Emergency Preparedness and Response

**Related Accreditation Element I.1.H.: The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.**

Organizations should develop plans to ensure sustainability of the HRPP and continuing protection of participants in research during emergencies. Although Element I.1.H., to which this relates, describes the essential requirements of an HRPP's emergency preparedness and response plan, this Tip Sheet describes emerging best practices and points organizations may wish to consider in developing emergency preparedness plans for their HRPPs. This Tip Sheet provides suggestions and examples of ways organizations can implement Element I.1.H., including what information could be included in an emergency preparedness plan for the HRPP; policies and procedures; and checklists, templates, and other materials.

Organizations should define responsibilities, roles, and workflows related to Element I.1.H.

When developing emergency preparedness and response plans appropriate to the size and complexity of the HRPP, organizations may wish to consider:

1. Assessing the risks of different types of emergencies and threats to the HRPP. A reason to consider different types of emergencies is that the appropriate response may be different. During an infectious disease pandemic, participants may be under government orders to stay home. For a hurricane or earthquake, trial participants may be under government orders to evacuate. Although no plan can address all possible emergencies, organizations can consider the following broad categories to evaluate how different types of emergencies may require different responses.
  - a. Organizations should consider infectious disease pandemics but also localized or regional infectious disease outbreaks. The impact of an infectious disease outbreak may vary significantly between an organization that primarily conducts social science research and one that conducts clinical research.
  - b. Extreme weather events or natural or human-caused disasters vary in terms of likelihood and impact. The threat that poses the greatest risk for one organization might be a hurricane; for others the greatest risk might be fires, earthquakes, or floods.
  - c. Many HRPPs rely upon online IRB or EC application and management systems and may depend on video conferencing

systems entirely to operate during a public health emergency. Organizations should assess the impact of not being able to access these systems during an emergency, as well as risks of cyber threats to online IRB or EC management programs.

- d. Evaluation of chemical, biological, radiologic, and nuclear threats may include risks posed by research labs, as well as external risks posed by industrial accidents and risks posed by terrorists events.
  - e. Organizations should assess the potential damage to the HRPP, which may vary based on the scale of the emergency. A local emergency, such as an industrial accident, may overwhelm local resources, but organizations may be able to obtain assistance from hospitals, universities, or research centers in the region to maintain continuity of operations of the HRPP. In contrast, regional events such as hurricanes or earthquakes mean that a greater number of organizations are impacted and assistance, if available, will be from organizations that are farther away. An infectious disease pandemic impacts all organizations, so there may be limited or no ability to obtain assistance from other organizations.
2. Assigning who is responsible for implementing an emergency preparedness plan for the HRPP, and whether there should be alternates in the event someone is not available to carry out this responsibility.
  3. Assigning who is responsible for periodically evaluating the emergency preparedness plan and making changes, when appropriate. (Element I.1.B.)
  4. Defining actions an organization may take during emergencies, short of stopping all research, including (Element I.1.B.):
    - a. Types of studies the implementation of which should be postponed.
    - b. Types of studies for which recruitment or enrollment should be halted but research activities continued on existing participants.
    - c. Types of studies that can continue via alternate mechanisms, such as the use of remote study visits, conference calls, or video conferencing.
  5. Developing education and training on expectations during emergencies. IRB or EC staff, other staff in the HRPP, and researchers and research staff need to be aware of what to do in the event of an emergency related to research. Organizations may wish to consider (Element I.1.E.):
    - a. Targeting educational requirements based on different roles and responsibilities – for example, for researchers, research staff, IRB or EC chairs, IRB or EC members, and HRPP staff, and departmental administrators.
    - b. Preparing educational materials to address emergency preparedness and response in advance of an emergency.
    - c. Preparing different educational materials based on specific issues faced in different emergencies.
    - d. Assigning who will be responsible for periodically reviewing and, when appropriate, updating educational materials.

- e. Developing educational materials in a transparent and inclusive manner with input from all parts of the HRPP and community groups.
6. Specifying how research teams are notified that the organization's emergency response plan has been activated and what researchers are expected to do.
7. Defining organizational criteria to triage the types of research that might continue and the types the organization may need to temporarily postpone. Examples of criteria that may be considered include whether research:
  - a. Presents a likelihood of direct benefit to participants.
  - b. Does not involve interaction or intervention that creates increased risks.
  - c. Involves direct interaction or intervention, but can manage risks by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or video conferencing, or by canceling in-person gatherings of people involving research activities and holding meetings such as focus groups and research-related activities, such as community advisory boards and participant and support groups for study participants
  - d. Will have an adverse impact on resources required to address the emergency.
8. Developing protocols and conducting scientific review in advance of an emergency as part of preparedness activities. In addition to creating approved protocols that can be implemented quickly, the exercise can train researchers and those conducting scientific review in the different issues posed by different emergencies. This may include adopting protocols already developed by other organizations. (Element I.1.F.)
9. Making arrangements in advance of an emergency to potentially rely upon other organizations for IRB or EC review temporarily during an emergency.

To make it easier to enter into agreements, organizations may want to participate in or adopt existing best practices and adopt existing standardized agreements to make it easier to quickly shift review of research to other organizations.
10. Obtaining IRB or EC review of sample protocols in advance of an emergency as an example of preparedness activities. In addition to creating approved protocols that can be implemented quickly, the exercise also helps train IRB or EC members and staff in the different issues posed by emergencies.
11. Developing continuity of operations plans for the infrastructure in the HRPP, which may include (Standard I-2):
  - a. How IRB or EC computer management systems will be kept functioning during emergencies, how the organization will function if essential computer systems are unavailable, and how the organization will return essential computer systems to service.
  - b. How the work of the HRPP will continue in the event of damage to offices and paper records.

- c. How the integrity of data will be maintained if computer servers on which research subject data is stored are destroyed.
  - d. How biospecimens repositories and research databases are protected during disasters, due to events such as loss of electric power or flooding.
  - e. How storage, handling, and control of drugs and medical devices will be maintained during the emergency. (See the US FDA's Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (March 2020).)
  - f. How security of research facilities will be maintained.
12. Developing incident response plans for all information technology systems necessary to operate the HRPP, including IRB or EC application systems, safety reporting systems, conflict of interest disclosure systems, and systems for communicating with researchers and research staff, study participants, IRB or EC members, and the community. For organizations that rely upon external vendors to provide systems used to operate the HRPP, the organization should ensure the vendor has a disaster recovery plan and that the plan meets the organization's requirements.
13. Developing guidance for clinicians and researchers on organization-wide changes that impact clinical care and research in similar ways, and clarifying that these do not require IRB or EC review. Examples of changes that do not require IRB or EC review include screening procedures mandated by the health care system in which a clinical trial is being conducted.
14. Describing strategies to ensure continuity of IRB or EC review during an emergency if it becomes impossible to continue to meet in person, which may include some or all of the following:
- a. Conducting review by the organization's IRB or EC via remote meetings instead of meeting in-person. (Element II.2.D.)
  - b. Relying upon external IRBs or ECs for review of some or all research during an emergency, even if the organization normally conducts review internally. (Standard I-9)
  - c. When relying upon external IRBs or ECs, written materials should describe which studies will be reviewed by an external IRB or EC.
    - (i) If the plan includes potential reliance upon external IRBs or ECs as part of the organization's emergency response plan, organizations should identify which IRBs or ECs it will rely upon and enter into reliance agreements in advance of an emergency or a master reliance agreement a range of organizations use.
    - (ii) Written materials describe recovery plans about how research that was transferred to external IRBs or ECs will return to the home organization from the external IRB or EC.
    - (iii) Organizations should endeavor to rely upon accredited IRBs or ECs as much as possible.
15. Developing ways organizations can exercise flexibility in oversight when research is not covered by regulations (for example, for unregulated

research, by extending continuing review dates during an emergency and allowing minor changes to be reported to the IRB or EC with requiring IRB or EC approval prior to implementation).

16. Developing alternate mechanisms for safety monitoring. If trial participants may not be able to come to the investigational site for protocol-specified visits, the IRB or EC should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible and would be sufficient to assure the safety of trial participants. (Element II.3.B.)
17. Considering more widespread use of waivers of documentation of consent for most minimal risk research that involves interaction with participants, to prevent the need to notify participants of changes to consent documents.
18. Evaluating whether researchers have emergency response plans in place for all their research locations. This might be based on whether the research is conducted at a university or hospital or dedicated research center, or whether the research will be conducted in a physician's office.
  - a. The need for response plans may be based on the type of research conducted and degree of risk in the event a study could not continue. A social science study may not require researchers to develop an emergency response plan. (Elements III.1.D. and III.1.E.)
  - b. Researchers must be knowledgeable that when planning to conduct research during emergencies, they should obtain IRB or EC approval in advance where possible. (Element III.1.A.)