



WORKSHEET: Protocol-Specific Emergency/Disaster Risk Mitigation Planning

The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator's ability ensure the ongoing safety of research subjects. Challenges to study conduct may arise, for example, from:

- Extreme weather events.
- Natural disasters
- Man-made disasters
- Infectious disease outbreaks

These challenges may lead to difficulties in conducting protocol-specified procedures, including administering or using test articles or adhering to protocol-mandated visits and tests. The following worksheet contains various considerations when investigators are responsible for protocol-specific emergency/disaster risk mitigation planning.¹

1. General Exclusions: If any of the following are true, development of a protocol-specific risk mitigation plan for research may not be needed.

- Research does not involve in-person interaction with research subjects.
- Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event.
- Research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.
- Research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event).

2. General Considerations for Creating a Protocol-Specific Emergency/Disaster Risk Mitigation Plan.

The following are additional considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during an emergency/disaster situation. The considerations below do not represent an exhaustive list and are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff, sponsors and institutional review boards (IRBs) in their efforts to address the new risks to research subjects and others posed by current or anticipated emergencies/disasters.

- Modifications to Recruitment and Enrollment Processes (Select any that are appropriate for the research.):

- Temporarily discontinue study recruitment efforts and initiatives.
- Temporarily discontinue enrollment of new research subjects.
- Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment (e.g., for infectious disease outbreaks).
- Other relevant actions should be taken. Describe: Click or tap here to enter text.

Additional Modifications to Minimize Risk (Select any that are appropriate for the research.):

- Withdraw some or all current research subjects from the research.
- Modify study visit procedures so that visits can be completed via phone.
- Modify study visit procedures so that visits can be completed virtually.
- Modify study visit procedures so that visits can be completed at subjects' local lab, clinical or imaging center.
- Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to in-person visits (e.g., for infectious disease outbreaks).
- Incorporate other additional safety monitoring procedures. Describe: Click or tap here to enter text.
- If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites.
- Modify timing and scope of specific study visits to account for essential versus nonessential study procedures.
- Other relevant actions should be taken. Describe: Click or tap here to enter text.

For FDA-Regulated Research: Modifications to Investigational Drug/Biologic/Device Access and Administration (Select any that are appropriate for the research.):

- For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery methods (e.g., investigational product can be shipped to the subject's residence).
- For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel).
- Other relevant actions should be taken. Describe: Click or tap here to enter text.

3. Research Record and Study Documentation Considerations when implementing

Emergency/Disaster-Specific Study Modifications: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects in emergency/disaster situations.

- For protocol wide study restrictions or modifications necessitated by the emergency/disaster situation, documentation related to any of the following elements are included in the research record where applicable and appropriate to the research:
 - Changes in study conduct
 - Duration of those changes
 - Which trial participants were impacted
 - How those trial participants were impacted

- Other relevant actions that were taken. Describe: Click or tap here to enter text.
- For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, the research record includes documentation related to the reasons for failing to obtain the efficacy assessment (e.g., identifying the specific limitation imposed by the emergency/disaster leading to the inability to perform the protocol-specified assessment).
 - Specific information in case report forms explains the basis of any missing data, including the relationship to the emergency/disaster for missing protocol-specified information.
- For FDA-regulated research where changes in the protocol include any of the following, the research record includes documentation that changes were made in consultation with the applicable FDA review division where feasible and appropriate:
 - Amendments to data management and/or statistical analysis plans
 - Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel)
 - Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens

4. Communication Plan to Subjects: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during emergency/disaster situations.

- A research subject communication plan describing the study-specific modifications being made to ensure the ongoing safety of research subjects during the emergency/disaster situation has been developed for implementation with all current (and where applicable, prospective) research subjects. This plan includes:
 - What information will be communicated to current (and where applicable, prospective) research subjects
 - Who will communicate the information
 - When the information will be communicated
 - How the information will be communicated

5. IRB Notification and Approval (Where Applicable): One of the following must be true.

- If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.
- For all other study modifications made to ensure the ongoing safety of research subjects throughout an ongoing emergency/disaster situation, a study amendment is submitted to the IRB

ⁱ This document satisfies AAHRPP elements I.1.H