



SOP: Response Plan for Emergencies-Disasters Impacting the HRPP

1 PURPOSE

- 1.1 This SOP establishes the process for initiating a response to an emergency/disaster situation impacting the HRPP or HRPP operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from:
 - 1.1.1 Extreme weather events.
 - 1.1.2 Natural disasters.
 - 1.1.3 Man-made disasters.
 - 1.1.4 Infectious disease outbreaks.
- 1.2 The process starts when an emergency/disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.
- 1.3 The process ends when the impact to the HRPP and the conduct of Human Research is assessed, and appropriate guidance is provided to HRPP personnel and the broader Human Research community.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 HRPP leadership defers to designated institutional leadership and institution-wide disaster and emergency response planning and limits HRPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans.
- 3.2 The HRPP evaluates its emergency response plans at least annually in accordance with the HRP-101 - Human Research Protection Program Plan and HRP-060 - SOP - Annual Evaluations of the HRPP.

4 RESPONSIBILITIES

- 4.1 The IRB Director or designee is responsible for carrying out these procedures.

5 PROCEDURE

- 5.1 If an emergency/disaster has occurred, or there is an imminent possibility of an upcoming emergency/disaster, assess the nature of the event and the appropriate response.
 - 5.1.1 Consult HRP-101 - Human Research Protection Program Plan to reference existing HRPP specific or institution specific emergency preparedness plans or information already in place.
 - 5.1.2 Contact the IO/OO and or designated institutional personnel responsible for institutional level emergency preparedness, and determine whether there are new or revised institution level emergency preparedness plans relevant to the current or anticipated emergency.

5.1.2.1 If yes, proceed in accordance with those plans and determine whether further contact or notification of the human research community is necessary.

5.2 Assess whether the emergency/disaster could impact HRPP operations:

5.2.1 If the current or anticipated emergency/disaster will prevent any upcoming IRB meetings from properly convening in-person, and an in-person meeting was planned, determine whether the meeting can be conducted virtually or via teleconference.

5.2.1.1 If yes, work with IRB members and staff to arrange for a virtual meeting. Follow HRP-040 - SOP - IRB Meeting Preparation to confirm quorum and availability of IRB members.

5.2.1.2 If a virtual meeting is also not feasible under the circumstances caused by the emergency/disaster, determine whether to cancel or reschedule the meeting(s).

5.2.1.3 If currently approved Human Research has or will expire prior to IRB review due to the IRB meeting cancelation/rescheduling, follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2 If IRB staff will be unable to complete their protocol processing and review responsibilities during the emergency/disaster, or if capacity will be limited for a period of time:

5.2.2.1 Work with the staff to use any available capacity to prioritize protocol processing, pre-review, and review of continuing review submissions.

5.2.2.2 If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2.3 Work with the IO/OO to notify the research community of the IRB Office's limited capacity to process and review submissions.

5.2.2.4 When the emergency/disaster no longer presents a limitation to IRB Office functions, work with the IO/OO to notify the IRB members and staff and research community that normal business operations have resumed.

5.2.3 If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.

5.2.3.1 If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO/OO to identify appropriate candidates for external IRB reliance and follow HRP-801 - SOP - Establishing Authorization Agreements.

5.2.4 If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with local IT support and or electronic system vendors to implement alternative procedures to access data/backup data.

5.3 Assess whether the emergency/disaster could necessitate additional flexibility in IRB review processes. If yes:

5.3.1 Review HRP-352 - WORKSHEET - Additional Emergency-Disaster Review Considerations with the IRB Chair(s) and staff in advance of upcoming IRB meetings.

5.3.2 Communicate to IRB Members (including Designated Reviewers performing non-committee reviews) that the additional considerations in the worksheet may be incorporated into IRB reviews where appropriate to maximize regulatory flexibility while continuing to assure research subject safety during the emergency/disaster.

5.3.3 Determine whether additional communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster and notify the community as appropriate.

5.4 Assess whether the emergency/disaster could impact some or all investigators' ability to conduct Human Research. If yes:

5.4.1 Notify the research community of the need for protocol-specific emergency/disaster risk mitigation planning. Use HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan.

5.4.2 Provide investigators with copies of (or links to) HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.3 Provide investigators with copies of (or links to) HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.4 If the emergency/disaster could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarify what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).

5.4.5 When the emergency/disaster no longer presents a limitation to Human Research activities, work with the IO/OO to notify the research community that normal business operations have resumed.

5.5 Evaluate whether the nature of the emergency/disaster may pose additional threats or risk to specific aspects of the institutions research activities or facilities. (For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some chemical, biological, or radiologic facilities to a greater extent than other facilities.)

5.5.1 If yes, and if broader institution-level emergency/disaster preparedness measures do not already address these specific activities or facilities, work with the IO/OO and appropriate institutional leadership to escalate and address any additional threats or risks.

6 MATERIALS

6.1 HRP-060 - SOP - Annual Evaluations of the HRPP

6.2 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

6.3 HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning

6.4 HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning

6.5 HRP-352 - WORKSHEET - Additional Emergency-Disaster Review

6.6 HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan

6.7 HRP-801 - SOP - Establishing Authorization Agreement

7 REFERENCES

7.1 AAHRPP Element I.1.H