

Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs and Office of Research Integrity & Compliance
Policy and Procedure

TITLE: Emergency Preparedness Plan for the Human Research Protection Program

PURPOSE:

To describe the process for initiating a response to an emergency impacting the human research protection program (HRPP).

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching, or research administration activities in support of the charitable and educational mission of HPHC/I.

POLICY:

HPHC/I has established this Emergency Preparedness Plan to ensure sustainability of the HRPP and continuing protection of participants in research during emergencies. This HRPP-specific plan is intended to complement emergency planning efforts by Point32Health, Inc. and HPHCI-wide response measures. All study personnel conducting human research should be aware of additional considerations associated with managing human research during an emergency/disaster scenario (e.g., extreme weather events, natural disasters, man-made disasters, infectious disease pandemics, etc.) and how they relate to ongoing interactions with research subjects and the Institutional Review Board (IRB).

PROCEDURE:

1. Routine Assessment of Emergency Preparedness Plan

The organization will routinely assess potential emergency scenarios and threats to the Institution to improve its emergency preparedness and response plan. The Office of Research Integrity and Compliance (ORIC) will collaborate with organizational leadership to develop, implement, and assess, emergency preparedness procedures for the HRPP. The ORIC will educate researchers and research staff regarding this policy and procedure.

2. Evaluation of an Emergency Event

- a. The Director, Research Integrity and Compliance Officer (DRICO) (or designee) will first communicate with the IRB Chair and/or the Institutional Official depending on the nature of the event to determine the types of research that might continue and the types that the organization may need to temporarily suspend.
- b. Depending on the nature of the event, the DRICO may also collaborate with HPHCI's Research Compliance Committee, the IRB, the Director, Office of Sponsored Programs, or the Vice President, Administration & Finance Institute.

- c. After the initial evaluation, the DRICO will communicate to IRB staff whether additional notification to researchers is needed. IRB staff will then communicate any required action or recommendations made to the investigator (or designee) via IRBNet. If the emergency impacts the IRBNet system, IRB staff will use email or phone to communicate to the investigator.
- d. The ORIC also responds to, and follows, HPHCI's Business Continuity Plan (BCP) led by the Manager of HPHCI, and is notified of any critical system failures in order to assess additional emergency events and system outages that may impact the HRPP.

3. IT/Systems Continuity

The IRB staff will work with HPHCI and Point32Health's IT resources and/or electronic system vendor, IRBNet, to ensure continuity of operations in the event that electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The DRICO (or designee) will collaborate with the vendor of the IRB's electronic system, IRBNet, to ensure that records are maintained on a secure server that is accessible in the event of an emergency.

4. Implementation of Alternative Review Procedures

HPHCI will leverage existing online and virtual platforms to ensure that IRB meetings can continue in scenarios where the IRB cannot meet in person. In instances where the convened IRB is unable to meet and IRB approval for a study may lapse, the IRB Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of already enrolled subjects.

The IRB regularly uses an Expedited Review procedure given the types of research conducted at HPHCI. Expedited Reviews are documented in IRBNet, in the event the emergency impacts the IRBNet system, reviews will be documented in email or on paper until the time the information can be added to the electronic record.

5. Voluntary Holds on Human Research Activities

Investigators may voluntarily elect to place all recruitment, enrollment, and research procedures on temporary hold during emergency/disaster scenarios if doing so will better ensure the safety of research subjects and would not create any additional risks to the safety and welfare of research subjects. Such voluntary holds on research activity do not require IRB notification or review.

6. Submitting Study-Specific Emergency/Disaster Risk Mitigation Plans for IRB Review

If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, the investigator will take action and notify the IRB within five business days according to the Policy and Procedure *Reporting and Review of Adverse Events, Protocol Deviations, Protocol Violations, and Unanticipated Problems*.

For all other study modifications made to ensure the ongoing safety of research subjects during emergency/disaster scenarios, the investigator must submit a study modification and all relevant new or modified study materials to the IRB according to the Policy and Procedure *Review of Modifications to Approved Research*.

REVISION HISTORY:

Department: Office of Research Integrity & Compliance	Title: Emergency Preparedness Plan for the Human Research Protection Program
Effective Date: 01/22/25	Owner: Research Compliance Specialist, QA/QI
Replaces P/P Dated: N/A	
Related Documents: Policy and Procedures: <i>Reporting and Review of Adverse Events, Protocol Deviations, Protocol Violations, and Unanticipated Problems; Review of Modifications to Approved Research</i> ; HPHCI Business Continuity Plan	
References: AAHRPP Elements I.1.H; AAHRPP Tip Sheets: Emergency Preparedness and Response	