Fred Hutch Cancer Center

Institutional Review Board

**Policy/Procedure**

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| **Title:** | HRPP Emergency Preparedness and Response Plan |
| **Version:** | 1.00 |
| **Effective Date:** | February 24, 2025 |
| **Responsible Office:** | Institutional Review Office (IRO) |
| **Responsible Official / Approved By:** | Meghan Scott, IRO Director |

## POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Center (Fred Hutch) to have a process for responding to an emergency situation that may affect the Fred Hutch human research protection program (HRPP) or HRPP operations. It is important to have appropriate plans in place to facilitate timely response in the case of emergencies to help ensure that the rights and welfare of research participants continue to be adequately protected. This policy is intended to complement areas of operations or human research protections not otherwise covered by institution-level emergency response plans. During an emergency, parties responsible for operation of the Fred Hutch HRPP will coordinate with designated institutional leadership and institution-wide disaster and emergency response at Fred Hutch or other locations at which Fred Hutch is engaged in research. Challenges to HRPP operations or the conduct of human research may arise from, but are not limited to, extreme weather events, natural disasters, man-made disasters, or emergent infectious disease outbreaks.

## DEFINITIONS

See *HRP-001 - Glossary of Terms and Acronyms* for full definitions of the following:

***Disaster***

***Emergency***: An event that requires immediate local, state, or federal assistance to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe.

***Human Research***

## INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to the IRO Director, IRO Assistant Director, IRB Operations Manager, IRO Coordinator Supervisor, and IRO Business Analyst Manager ("IRO leadership").

## PROCEDURES

The process starts when an emergency situation affecting 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.

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 Fred Hutch human research community.

1. **Assessment of the Emergency**

    a. If an emergency has occurred, or there is an imminent possibility of an upcoming emergency, assess the nature of the event and the appropriate response.

i. Consult Fred Hutch institutional level emergency preparedness plans or information already in place.

ii. Contact the Institutional Official (IO), Vice President and Chief Compliance Officer (CCO), 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.

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

**2. Assessment of Impact on HRPP Operations**

a. If the current or anticipated emergency will prevent any upcoming IRB meetings from properly convening, determine whether the meeting can be conducted via alternate means, (e.g., alternate location, virtually, or teleconference), and/or with alternate members, or must be rescheduled or canceled.

b. Determine whether IRB staff will be able to complete submission processing, and the IRB will be able to fulfill its review responsibilities during the emergency.

i. If capacity of staff or the IRB will be limited for a period of time, work with the IO/CCO to notify the research community of the IRB's limited capacity to process and review submissions.

ii. If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is necessary for new study submissions or whether a transfer of research to an external IRB(s) is necessary for existing studies.

1. If the necessary reliance agreements are not currently in place, identify appropriate candidates for external IRB reliance and follow *HRP-130 - POLICY - IRB Reliance Agreements*.

iii. If currently approved human research has or will expire prior to IRB review because of impacts to HRPP operations, follow *HRP-111 – POLICY – Closure and Re-Open* related to an IRB lapse in approval.

c. If data or records (paper or electronic) are unavailable during the current or anticipated emergency, implement alternative procedures to access data/backup data by consulting with:

i. As necessary, for accessing paper files, Fred Hutch Security, Facilities Engineering, or Shipping, Receiving and Mail Services

ii. For electronic systems, IT support and/or electronic system vendors.

d. Assess whether the emergency could necessitate additional flexibility in IRB review processes. Work with the IRB chairs, as needed. If additional flexibility is appropriate, communicate to IRB members and IRB staff the additional considerations to maximize regulatory flexibility, and to the research community as appropriate, while continuing to assure research subject safety during the emergency. Areas of flexibility include:

i. Use of waivers of documentation of consent for minimal risk research

ii. Alternate mechanisms for safety monitoring in lieu of in-person study visits, when applicable, if appropriate (e.g., phone contact, virtual visit, alternative location for assessment)

iii. For research not subject to federal regulations, extending continuing review dates during the emergency, and/or allowing minor changes in research to be reported to the IRB without requiring IRB approval prior to implementation

iv. When institutional or federal guidance or communications related to managing research during the emergency provides additional flexibility or resources.

v. Reminder that researchers may forego prospective IRB approval for changes in research if the change is "necessary to eliminate apparent immediate hazards to research participants" in accordance with *HRP-119 – POLICY – Modification to Ongoing Activities*

3. **Assessment of Impact on Human Research**

    a. Assess whether the emergency could impact some or all investigators' ability to conduct human research. If yes:

        i. Notify the research community of the need for protocol-specific emergency risk mitigation planning.

        ii. Provide investigators with copies of (or links to) *HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning* and *HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning*.

        iii. If the emergency could impact clinical care standards, which could in turn impact research, develop guidance for researchers that clarifies 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).

    b. Evaluate whether the nature of the emergency may pose additional threats or risk to specific aspects of Fred Hutch 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.)

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

4. **End of Emergency**

    a. When the emergency no longer presents a limitation to IRB functions and/or human research activities, notify the IRB members, IRB staff, and the research community that normal business operations have resumed.

5. **Periodic Changes to the HRPP Emergency Preparedness and Response Plan**

    a. This policy will be reviewed at least bi-annually.

    b. Have the IO/CCO or designee evaluate the HRPP's emergency preparedness plan and make changes when appropriate.

        i. When updates to the HRPP emergency preparedness plan are made, the IRB Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.

## SUPPORTING DOCUMENTS

HRP-001 - Glossary of Terms and Acronyms
HRP-063 - POLICY - Suspension or Termination of IRB Approval
HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning
HRP-111 - POLICY - Closure and Re-Open
HRP-119 - POLICY - Modification to Ongoing Activities
HRP-130 - POLICY - IRB Reliance Agreements
HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning

## REFERENCES

None

## VERSION HISTORY

| Version | Effective Date |
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