

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Office for Human Subject Protection</b>		<b>Effective Date: 12/01/2024</b>
	<b>The Human Research Protection Program Emergency Preparedness</b>		<b>Policy 105</b>

## POLICY

### 1. Purpose

Establish an HRPP emergency preparedness process within the University of Rochester (UR) to ensure to protect the rights and welfare of human subjects in the event of an emergency or disaster situation. Potential crises may include (but are not limited to): natural disasters, man-made disasters, extreme weather impacts, and/or disease outbreaks.

The process begins when identification of an imminent emergency/disaster situation that may impact the HRPP occurs, or scenarios where an emergency situation takes place and HRPP operations and/or the ability of investigators to conduct human subject research is, or is likely to be, adversely impacted. The process ends when the impact to the HRPP and the conduct of human subject research is assessed, and appropriate guidance is provided to University's HRPP community.

### 2. Scope

This policy applies to all human subject research conducted or supported by employees or agents of the UR.

### 3. Definitions

None

### 4. References

- 4.1. [HHS Effects of Disasters on Human Research Protections Programs Guidance \(May 14, 2008\);](#)  
[FDA Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies \(September 2023\)](#)
- 4.2. [Policy 101: Maintenance of Policies](#)  
[Policy 102: University of Rochester Human Research Protection Program;](#)  
[Policy 201: Education Program;](#)  
[Policy 501: Levels of RSRB Review;](#)  
[Policy 504: IRB Reliance and Collaborative Research;](#)  
[Policy 901: Investigator Responsibilities;](#)  
[Policy 1001: Quality Improvement Program;](#)
- 4.3. [University of Rochester Emergency Action Plan](#)  
[University of Rochester Emergency Management](#)  
[University of Rochester Policy 0BCM02 Business Continuity Management Policy](#)

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## 5. Responsibilities

- 5.1. UR-HRPP leadership defers to designated University of Rochester leadership and institution-wide disaster and emergency response planning and limits HRPP-specific disaster and emergency response planning only to those areas of operations related to human research protections not otherwise covered by institution-level plans.
- 5.2. The UR-HRPP evaluates its emergency response plans in accordance with *Policy 101: Maintenance of Policies*.
- 5.3. The Associate Vice President for Human Subject Protection or designee is responsible for carrying out these procedures.
- 5.4. UR-HRPP leadership will coordinate to maintain awareness of emergency-related policies, new information, revised materials, and training opportunities to the UR-HRPP community. This includes:
  - 5.4.1. Communicating policy-related information, updates, and instructions to the UR-HRPP community via standard communication routes.
  - 5.4.2. Posting policy-related information, updates, and instructions to the UR-HRPP community to the OHSP website.
  - 5.4.3. Preparing educational materials to address emergency preparedness and response, including, when appropriate, targeted materials based on roles/responsibilities (e.g., for OHSP staff, and RSRB members, researchers, and research staff).
  - 5.4.4. Periodically reviewing updating educational materials, per item 5.2 above.

## 6. Requirements

- 6.1. 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. The Associate Vice President for Human Subject Protections will contact the Institutional Official (IO) and/or designated personnel responsible for institutional emergency preparedness and determine whether there are new or revised institution level emergency preparedness plans relevant to the current or anticipated emergency.
  - 6.1.1. If yes, proceed in accordance with those plans and determine whether further contact or notification of the UR-HRPP community is necessary.
- 6.2. Assess whether the emergency/disaster could impact RSRB operations:
  - 6.2.1. If the current or anticipated emergency/disaster will prevent any upcoming RSRB meetings from properly convening in-person planned meeting, determine whether the meeting can be conducted virtually or via teleconference.

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- If yes, work with RSRB members and staff to arrange for a virtual meeting. Confirm quorum and availability of IRB members.
  - If a virtual meeting is also not feasible under the circumstances caused by the emergency/disaster, determine whether to cancel or reschedule the meeting.
- 6.2.2. If currently approved human subject research has or will expire prior to RSRB review due to the RSRB meeting cancelation/rescheduling, follow *Policy 501: Levels of RSRB Review*.
- 6.2.3. If RSRB 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:
- Work with the staff to use any available capacity to prioritize protocol processing, pre- review, and review of continuing review submissions.
  - If currently approved human subject research has or will expire prior to RSRB review due to IRB office capacity limitations *Policy 501: Levels of RSRB Review* is to be followed.
  - Work with the IO to notify the UR-HRPP community of the RSRB’s limited capacity to process and review submissions.
  - When the emergency/disaster no longer presents a limitation to RSRB Office functions, work with the RSRB Director to notify the RSRB members, staff and UR-HRPP community that normal business operations have resumed.
  - If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.
  - If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO to identify appropriate candidates for external IRB reliance and follow *Policy 504: Reliance and Collaborative Research*.
  - If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with Research IT support and or electronic system vendors to implement alternative procedures to access data/backup data.
- 6.2.4. Assess whether the emergency/disaster could necessitate additional flexibility in RSRB review processes. If yes:
- Review the emergency-disaster plan considerations with the RSRB Chair(s) and staff in advance of upcoming IRB meetings.
  - Communicate with RSRB Members (including Designated Reviewers performing non-committee reviews) regarding the additional considerations

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that may be incorporated into RSRB reviews where appropriate to maximize regulatory flexibility while continuing to assure research subject safety during the emergency/disaster.

- Determine whether additional communications to the UR-HRPP community are necessary to inform investigators of any additional measures the RSRB will take place to maximize regulatory flexibility during the emergency/disaster and notify the UR-HRPP community as appropriate.

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

- Notify the research UR-HRPP community of the need for protocol-specific emergency/disaster risk mitigation planning.
- If the emergency/disaster could impact clinical care standards which in turn could impact research, develop guidance for researchers to clarify what does and does not require RSRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).
- When the emergency/disaster no longer presents a limitation to human subject research activities, work with the IO to notify the research UR-HRPP community that normal business operations have resumed.

6.2.6. 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).

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

6.3. Assess whether the emergency/disaster could impact Education Program operations:

6.3.1. Assess whether the emergency/disaster could impact the UR-HRPP community's ability to administer and monitor Human Subject Protection (HSP) training requirements. If yes:

- Consult electronic system vendors, and/or Research IT to implement alternative procedures to maintain training access and documentation.
- Determine whether the emergency/disaster could necessitate flexibility in HSP training requirements and notify the UR-HRPP community, as appropriate.

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6.3.2. Assess whether the emergency/disaster could impact other training opportunities/resources available via the Education Program. If yes, consult with applicable designated University officials (e.g., Digital Communications, Center for Experiential Learning, University IT).

6.4. Assess whether the emergency/disaster could impact Quality Improvement (QI) Program operations:

6.4.1. Assess whether the emergency/disaster could impact the QI division's ability to conduct QI reviews and consultations. If yes:

- Revert to paper-based review and consultation processes and documents. While these documents are held electronically, they can be recreated based on QI employee experience.
- Consult electronic system vendors and/or Research IT to implement alternative procedures to maintain QI process documentation.
- Determine whether the emergency/disaster could necessitate flexibility in QI requirements, as appropriate.

6.4.2. Assess whether the emergency/disaster could impact other available QI program opportunities/resources. If yes, consult with applicable designated University officials (e.g., IO, University IT).

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None

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None

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None

**Approved By:**

Signed by:

*Elizabeth Kipp Campbell*



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