CONTINUITY OF OPERATIONS PLAN

Human Research Protection Program

Last updated March 10, 2025

Purpose

This Continuity of Operations Plan (COOP) is meant to guide the development of contingency plans to support operations in the Human Research Protection Program (HRPP) during an emergency, disaster, or significant disruption to university systems affecting institutional or research operations. All U-M units are expected to prepare and maintain up-to-date plans, covering the areas of essential functions, staffing, supplies, contract services, communications, travel, and contingency planning.

Planning Principles

- In the event of an emergency, disaster, or significant disruption to university systems, some services will need to be stopped, and others will be provided differently.
- Existing resources and mechanisms will be leveraged when possible.
- Staffing will be modified as necessary to prioritize critical functions.

Review And Distribution

- The plan is shared annually with all HRPP staff. Institutional Review Board (IRB) and HRPP Unit Directors are responsible for training unit staff on expectations during an emergency on an ongoing basis and as necessary following changes.
- IRB Directors will share information outlined in this plan with the IRB Chairs and members.
- The plan is reviewed annually at the beginning of each fiscal year by the HRPP Associate Director. The HRPP Director, the IRB Directors, and the Associate Vice President for Research-Clinical and Human Subjects Research review updates to the plan.
- Updates will be communicated, as necessary, to HRPP staff, IRB Chairs and members, and the broader research community.
- Investigators and study teams will be informed of plan through announcements, emails, the HRPP newsletter, and the HRPP website. A version of this plan is posted to the HRPP website.
- Questions regarding this plan should be directed to: hrppumich@umich.edu .

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Section 1: Department / Unit Information

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Ann Arbor, MI 48109-2800

HRPP Administrative Assistant:	734-763-3968
Department Hours of Operation:	Monday-Friday 8am-5pm
Department Fax:	734-936-1852
Department-Wide Email:	HRPP.Team@umich.edu

Department Leadership:	Julie Lumeng, Associate Vice President for Research-Clinical and Human Subjects Research
	Judith Birk, Assistant Vice President for Research – Human Research Protection Program, HRPP Director
	*Kate Sasamoto, HRPP Associate Director

*Designated as the lead emergency coordinator/planner responsible for preparing this plan.

Department Emergency Contacts:

Name and Title/Role	Business Contact Information
Julie Lumeng Title/Role: Associate Vice President for Research-Clinical and Human Subjects Research, University of Michigan Office of Research	Email: jlumeng@med.umich.edu
Judith Birk Title/Role: HRPP Director Assistant Vice President for Research - Human Research Protection Program	Email: jbirk@med.umich.edu
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Lana Gevorkyan Title/Role: IRB Coordinated Services and Practices (CSP) Director	Email: gevorkla@umich.edu

Section 2: Functions

The HRPP And Essential Functions:

The HRPP's primary function is to oversee human subjects research. The units and services affiliated with the HRPP include the Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS), the University of Michigan Medical School's Institutional Review Boards (IRBMED), the Office of Research and Compliance Review (ORCR), Minors in Research Compliance Monitoring, the Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee, and Coordinated Services and Practices (CSP).

This plan addresses when the following may affect the HRPP's ability to perform essential functions or require the implementation of emergency mitigation strategies impacting the type of research that would be allowed to proceed/continue:

- Local, regional, or national natural or man-made disasters (e.g. weather-related events, infectious disease pandemic, supply shortage).
- Emergencies, such as local security incidents or national security emergencies (e.g. chemical, biological, radiologic, and nuclear threats).
- Significant anticipated reduction of staffing levels.
- Critical infrastructure outages (e.g. electricity, network, and/or University systems outages) that impact the ability of the HRPP to perform essential functions.

Procedures and staffing for the oversight of human subjects research, depending on the event or situation, may require the implementation of emergency mitigation strategies impacting the type of research that would be allowed to proceed/continue and/or the reduction of HRPP services/functions.

HRPP Work Redesign And Redeployment Strategies:

The HRPP has established an emergency response committee, consisting of HRPP leadership and Directors from HRPP units. If a trigger/dependency as outlined above occurs, the HRPP emergency response committee will convene to discuss work redesign and redeployment strategies in the specific context of the event triggering the emergency response. The IRBMED has established a COOP that will serve as the basis for IRB response regarding the review, approval, and oversight of human research.

Generally, the HRPP emergency response committee will consider the following strategies:

- Staffing:
  - If staff are unable to report in person, cancel any in-person work/activities, and direct staff to work remotely until the situation is resolved.
  - Triage work to give the highest priority to participant safety measures, deadline-driven activity and redeploy available staff to those projects.
- Postponement or halt of research:
  - Identification of types of studies the implementation of which should be postponed.
  - Identification of types of studies for which recruitment or enrollment should be halted but research activities continued on existing participants.
  - Identification of types of studies that can continue via alternate mechanisms, such as the use of remote study visits, conference calls, or video conferencing.
  - Examples of studies that the HRPP could decide may continue or be newly implemented are those that:

    - Present a likelihood of direct benefit to participants.
    - If the study is active, discontinuing the study would present a high degree of risk to participants (e.g., implanted device)
    - Do not involve interaction or intervention that creates increased risks.
    - Do not adversely impact resources required to address the emergency.
    - Involve direct interaction or intervention but risks can be managed by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or video conferencing.
- IRB Review:
    - Continue to convene IRB meetings remotely or by teleconference per institutional policies.
    - Allow for ad hoc IRB meetings if rapid turnaround is required to review submissions impacting participant safety per IRB standard operating procedures.
    - As appropriate, use of waiver of informed consent and/or waiver of documentation to minimize the need to minimize unnecessary interactions with participants.
    - Develop alternate mechanisms for safety monitoring. If trial participants may not be able to come to the investigational site for protocol-specified visits, the IRB could evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) may be implemented when necessary and feasible and would be sufficient to assure the safety of trial participants.
    - Exercising flexibility in oversight when research is not covered by federal regulations (for example, by extending continuing review dates during an emergency and allowing minor changes to be reported to the IRB following implementation).
    - Rely on external IRBs to provide a review of U-M research per master agreements.
- Contact federal agencies to request relief from deadline requirements, as appropriate.

Section 3: Essential Resources

eResearch is the University of Michigan's site for electronic research administration. The eResearch Regulatory Management (eRRM) web-based system centralizes the review and approval processes for the U-M Institutional Review Boards.

If eRRM is unavailable for an unknown duration or spans more than one business day, the HRPP would depend on email or other forms of communication with PIs and study teams. The HRPP will also coordinate with U-M Information and Technology Services regarding reporting and identifying mitigation strategies due to the loss of eRRM. Mitigation strategies could include the creation of emergency forms for the submission of priority research, required amendments, adverse events, or other reportable information and/or a triage system to prioritize submissions.

Section 4: Communications

Internal Communication Plan with HRPP Employees:

Internal communications between HRPP staff will take place using one or more of the following methods: (1) phone, (2) virtual/video call meetings, (3) internet/e-mail/text, and (4) in-person (if possible).

If necessary, the HRPP emergency phone tree will be utilized to alert all HRPP staff of the emergency and implementation of this plan.

Internal communications between HRPP staff and other U-M units will take place using one or more of the following methods: (1) phone, (2) virtual/video call meetings (3) internet/e-mail/text, and (4) in person (if possible).

Communication Plan with Research Community:

Communications between the HRPP and the research community will be coordinated between HRPP leadership and the HRPP Communications Specialist. Information related to emergency mitigation strategies impacting research and/or reduction of HRPP functions or services will need to be communicated to Principal Investigators and study teams. Communication with the research community will take place using one or more of the following methods: (1) the HRPP Pulse Newsletter (2) email announcements (3) the HRPP website (4) informational webinars.

The HRPP Communications Specialist has access to email distribution lists that identify all study team members on an active or submitted IRB application as well as staff from other research support units that can be utilized for emergency communications. In addition, the HRPP Communications Specialist will work with HRPP leadership and other University units to identify other email distribution lists, newsletters, or websites that the HRPP can utilize to communicate information broadly.

External Communication Plan with Non-University Stakeholders:

External communications between HRPP staff, regulatory agencies, state and local health departments, and emergency response agencies will take place using one of the following methods: (1) phone, (2) virtual/video call meetings (3) internet/e-mail/text, and (4) in person (if possible).

Any broad or public communication to non-University stakeholders should be coordinated through the University of Michigan Office of the Vice President for Research.

Section 5: Campus Closures / Reduction in Operations

If the University declares an emergency reduction in operations (i.e. closes campus) consistent with Regents' Standard Practice Guide 201.27, HRPP units shall also close on-site operations.

HRPP staff shall be notified using the emergency notification procedures outlined in Section 10.

Staff should work remotely, and if necessary, triage all time-sensitive, deadline-driven activities (see Section 2, Part 1 for additional triage recommendations) and seek assistance whenever needed.

Section 6: Selected Federal Agency Emergency Deadline Policies

HRPP leadership, in coordination with OVPR as necessary, will notify, in writing or by phone, federal and other agencies regarding an event that triggers this plan that results in emergency mitigation strategies and/or a reduction in HRPP services or functions. Notification may include the following agencies and entities:

- Office for Human Research Protections
- Food and Drug Administration
- National Institutes of Health

- National Science Foundation
- Centers for Disease Control and Prevention
- Association for the Accreditation of Human Research Protection Programs

Other agencies or entities may also be notified.