



**Institutional Review Board Standard
Operating Procedure (SOP):
Continuity of Operations (COOP):
Preparedness and Response**

General Information	
Process Title: Institutional Review Board COOP: Preparedness & Response	Division: PHSPM
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SOP Purpose

This Standard Operating Procedure is presented as a support document to the Institutional Review Board HRPP Emergency Preparedness Policy DOHP 5-5d-4.10 and to specifically address the steps to ensure a continuity of operations (COOP) for research participants and partners during emergencies at the headquarters and local levels.

Process Overview

Process Description:

The Department of Health (Department) is required to maintain a comprehensive Human Research Protection Program (HRPP) emergency preparedness and response plan to ensure the protection of research participants' rights and welfare during emergencies. The Department recognizes that various emergencies may create challenges to Institutional Review Board (IRB) operations, research conduct, and the safety of research participants.

This standard operating procedure (SOP) is developed to support the Institutional Review Board HRPP Emergency Preparedness policy DOHP5-5D-4.10, and to provide reasonable, common-sense, and

accepted practices to utilize during any declared emergency that may disrupt the ability of the department's office and research participants to carry out and complete the obligations under existing agreements. As with the policy, this SOP applies to all research activities under the jurisdiction of the HRPP Department, including all IRB members, staff, researchers, research staff, and other personnel involved in human subject's research.

Authority & Supporting References

I. Authority:

- a. Chapter 381.86, Florida Statutes, Institutional Review Board

II. Supportive Data and References

- a. Institutional Review Board HRPP Emergency Preparedness Policy DOHP 5-5d-4.10
- b. Department of Health Emergency Preparedness Plan

Definitions:

Alternate Site – An alternate site is a secondary or tertiary site identified in the event an IRB participant may be required to relocate due to declared emergency. The site should contain the necessary resources and access for the participant to complete required tasks.

Continuity of Operations (COOP) – The process of continuing statutorily, department, or program required objectives, tasks, and outcomes during any declared emergency that disrupts services and environments. COOP plans should include the capability to continue essential HRPP functions during an emergency through pre-planned procedures and alternate methods.

Continuity of Government (COG) – The process of continuing the oversight, management, review and approval of the objectives, tasks, and outcomes during any declared emergency that disrupts services and environments. COG plans should include the capability to continue essential HRPP functions during an emergency through pre-planned procedures and alternate methods.

Declared Emergency – Any natural disaster, extreme weather event, man-made disaster, biological emergency, cyber security incident, public health emergency, or other unforeseen event that may impact HRPP operations, research conduct, or the safety and welfare of research participants. A declared emergency may be a local or statewide event.

- **Types of Declared Emergency:**

- **Biological Emergencies** - Conditions or diseases of significant public health concern that result in economic loss and require substantial response efforts by the Department.
- **Cyber Security Incident** - Any event that results in unauthorized access to, disruption of, or compromise of information systems, data, or technology infrastructure supporting HRPP operations.

- **Extreme Weather Events** - Meteorological events that pose a barrier to typical daily functions and services.
- **Man-made Disasters** - Human-induced circumstances that result in the loss of property, life, or the ability to carry out critical functions.
- **Risk Assessment** - The systematic evaluation of potential emergencies and their likely impact on HRPP operations and research participant safety.

Event Coordinator – A department employee assigned the responsibility of directing and managing any declared activities in preparation and response to a declared emergency.

Incident Commander – A staff member of the department assigned the responsibility and oversight of any declared emergency conducted at the highest levels of Executive Management. This assignment would coordinate incident command team activities.

Process Steps by Section of Required Activity:

Section III: Roles and Responsibilities

- I. A member of the Office of Public Health Research within the Division of Public Health Statistics and Performance Management will be assigned the role of Event Coordinator and will work with the local partners of IRBs to ensure COOP & COG. This duty will be included in the position description of the assigned staff member.
- II. Identify Department Response Team
 - a. The Event Coordinator will identify an internal response team for IRB participants if necessary. Team members will be given specific duties to ensure efficient and effective operations for preparedness and response.
 - b. The Event Coordinator will develop a preparedness/response plan that will include and address the following areas:
 - i. Develop a succession plan of department staff assigned to the response team.
 - ii. Identify Essential Services that must be continued, even with reduced staff or from another location.
- III. Identify Alternate Sites
 - a. The Event Coordinator will work with IRB participants to identify and record alternate sites in the event a declared emergency renders the primary location unusable. The Event Coordinator will also determine secondary and tertiary sites for the Headquarter Office staff in Tallahassee to ensure COOP & COG, as well as access for IRB participants.

IV. Develop/Implement Communication Plan

- a. The Event Coordinator will develop and implement a communication plan to activate in the event of a declared emergency. The communication plan should include the following elements:
 - i. Pre-event contact plans to participants in projected impact areas with instructions on preparation.
 1. Updated contact information for each local participant.
 2. Designated primary points of contact in each identified area.
 3. Types of notifications and schedule of release.
 - ii. During event contact plan to gather information used in assessing needs and level of required support.
 1. Develop a template for reporting status and addressing needs.
 - iii. Post-event contact plan to ensure recovery procedures are implemented and for the preparation of the after-action report for management.
 1. Develop a process for collecting, compiling and reporting recovery information.
 2. Develop or adopt existing template for reporting status.
- b. The Event Coordinator will determine the most effective and efficient notification system/methodology for use by team/partners/customers to ensure continuous communication until the end of the event or declared emergency.

Section IV: Plan Review and Training

- I. The IRB Coordinator and the Even Coordinator should conduct an annual emergency exercise(s) to test and review the COOP & COG. There should be an annual scenario specific tabletop exercise conducted with all participants on a statewide basis. Exercises may also be conducted with local areas either on request or to review local preparedness protocols.
- II. All exercises should include an after-action assessment to measure the strengths, weaknesses, outcomes, and threats to the response plan.
- III. Specific areas to be tested should include but not be limited to:
 - a. The ability to contact designated primary points of contact.
 - b. The success of the communication plan in the pre, during, and post notification process.
 - c. The tools for collecting, compiling, and reporting information.
 - d. The efficiency and effectiveness of an impacted area moving to a back-up site to continue operations.
 - e. The safety and welfare of participants in the impacted area.
 - f. The effectiveness of the data systems, record keeping, reporting of research, and meeting the required deadlines in the impacted area.
 - g. The effective level of support from the IRB Central Office (HQ).
- IV. An After-Action (post-wash) meeting should be conducted with participants at a designated time after the exercise to discuss findings and results.
 - a. The findings and results will be used to revise, update, or strengthen the emergency response plan.

Section IV: Deactivation and Reconstitution Process

- I. Ceasing Event Activities
 - a. When the disaster or emergency no longer poses a risk to life or property, the IRB Coordinator and Event Coordinator will notify the investigators and the IRB Chairs and members, that normal operations have resumed.
 - b. The IRB Coordinator and Event Coordinator will develop and present the final after-action report to management.
 - i. The report will include any recovery or reconciliation actions taken in the area impacted.
 - ii. The report will include any activity projected to be delinquent in submission or in capabilities to perform required tasks.
 - iii. The report will include any system security or data breach and the actions taken to remediate the breach.
 - c. Participants will formally request extensions as outlined in the DOHP 5-5D-4.10 to complete tasks and to avoid non-compliance.
- II. Recovery and Close Out
 - a. If an alternate site was activated, the Event Coordinator and the primary point of contact for the impacted area will submit a plan for the deactivation of the alternate site and a timeline for returning to the primary site of operations.
- III. The HRPP Director, IRB Coordinator and Event Coordinator will make the determination to close the event after all recovery aspects have been met.