

1.34 Emergency Preparedness for the Office of Regulatory Affairs and IRBs

1.0 Purpose

The purpose of this policy is to describe the Emergency Preparedness and Continuity of Operations Plan (EP/COOP) for the HRPP. This policy and accompanying documents focus on the Office of Regulatory Affairs (ORA) and the IRB; the Organization maintains plans for other components of the HRPP.

2.0 Policy

It is the policy of the Organization that:

- 2.1. The HRPP has an Emergency Preparedness and Continuity of Operations Plan, appropriate to the size and complexity of the HRPP, that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency.
 - 2.2. The HRPP Emergency Preparedness and Continuity of Operations Plan is periodically evaluated and, when necessary, adjusted to ensure continuity of operations.
 - 2.3. Education about the HRPP Emergency Preparedness and Continuity of Operations Plan will be provided to IRB members and staff, researchers and research staff, and other persons in the HRPP as appropriate.
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3.0. General Comments

- 3.1. The purpose of the attached Emergency Preparedness /Continuity of Operations Plan (EP/COOP) is to provide the framework for restoring essential functions to the ORA and the UNMC IRBs as components of the HRPP in the event of an emergency that affects its operations. It is a supporting document to the UNMC/Nebraska Medicine (NM) enterprise COOP Plan.

The attached document establishes the EP/COOP procedures for any operational disruption, including but not limited to:

- Loss of access to a facility (such as damage to the building),
- Loss of service due to a reduced workforce (such as due to pandemic virus) and
- Loss of service due to protracted equipment or systems failure (such as IT systems failure).

The intent of this HRPP EP/COOP is to lay out procedures to allow the ORA and IRBs, as components of the HRPP in the event of an emergency, to implement actions to promptly begin continuity operations and to maintain essential functions until full operative capacity can be resumed.

- 3.2. Depending on the nature of the risk and the potential impact to the HRPP and the institution, the AVCRA, in consultation with the IO, the Executive Chair and IRB Chairs, and representatives from components of the HRPP as appropriate, will determine which actions need to be undertaken to minimize the impact on research activities and mitigate risk to research participants, study team members, and the institution.
 - 3.3. The ORA and IRBs, as components of the HRPP, will work with the appropriate Institutional personnel (Director of UNMC Office of Emergency Management and Nebraska Medicine Executive Director of Emergency Management and Biopreparedness) to coordinate activities as appropriate with Institutional plans already in place to address the event (as per the institutional COOP plan on file with the UNMC Office of Emergency Management).
 - 3.3.1. If the emergency only affects the ORA or IRBs, the ORA will assure that appropriate Institutional personnel (Director of UNMC Office of Emergency Management and Nebraska Medicine Executive Director of Emergency Management and Biopreparedness) are informed.
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4.0. Specific Responsibilities in the Event of an Emergency

- 4.1. Specific responsibilities are described in the attached EP/COOP document.
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5.0. Specific Actions by the ORA and/or IRBs in the Event of an Emergency

- 5.1. Specific actions are described in the attached EP/COOP document.
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6.0. EP/COOP Maintenance

- 6.1. The Associate Vice-Chancellor for Regulatory Affairs will periodically review (at least biennially) and update the UNMC HRPP EP/COOP based on legislative changes, UNMC/NM guidance, departmental or personnel changes, and procedural changes based on lessons learned from exercises and actual events.
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7.0. Training and Education

The ORA will provide targeted communications and education/training regarding the UNMC HRPP EP/COOP to researchers and research staff, IRB Chairs and IRB members, study team members and PIs. As appropriate, the ORA, in collaboration with the UNMC and NM Office of Emergency Management will conduct periodic exercises to assure validity and operability of the plan.

Addendum

See [UNMC HRPP EP/COOP plan](#)

DOCUMENT HISTORY

? Written: 8/31/2023 (Approved: 9/1/2023) {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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