Emergency Preparedness /Continuity of Operations Plan (EP/COOP)

1.0 Emergency Preparedness /Continuity of Operations Plan (EP/COOP)

- 1.1. Purpose

The UNMC Office or Regulatory Affairs (ORA) and the Human Research Protection Program (HRPP) is committed to the safety and protection of research participants, as well as ORA and HRPP staff, and investigators and research staff, and the operations and facilities of the research enterprise.

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

- 1.2. Scope

This document applies to all personnel in the UNMC HRPP office and all locations where essential functions of the UNMC HRPP are conducted. It also applies to the array of emergencies and hazards that could threaten the performance of essential HRPP functions. The plan covers the Human Research Protection Program and the UNMC Institutional Review Board.

This plan does not apply to temporary disruptions of service including temporary disruptions in IT systems or power outages and any other scenarios where essential functions can be readily restored in the primary facility within 3 business days.

- 1.3. Responsibility

It is the responsibility of the entire team to ensure the success of the UNMC HRPP EP/COOP implementation during and after an emergency; however, there are specific roles that hold explicit responsibility and decision-making authority during implementation.

Implementation and operationalizing of the UNMC HRPP EP/COOP: The COOP Coordinator will act as the primary point of contact (POC) for all members of the HRPP team regarding day-to-day operations of the HRPP EP/COOP. The COOP Coordinator will initiate appropriate internal and external notifications, support the decision-making procedures of the Director of the ORA (Assistant Vice-Chancellor for Regulatory Affairs; AVCRA) and Institutional Official (IO), and maintain the UNMC HRPP EP/COOP for the duration of the emergency to ensure the essential functions of the HRPP.

- The specific person assigned as COOP Coordinator will be evaluated on a regular (at least annual) basis, and as part of the review of the general EP/COOP. As possible, two coordinators will be assigned: one local, and one remote. Depending on the nature and extent of the emergency, and the HRPP and ORA systems disrupted, the appropriate person will be designated by the AVCRA.

In addition, the IO and designee, the Institutional Review Board (IRB) Executive Chair, Chairs, and Vice-Chairs; UNMC and NM leadership; and the Safety /Compliance team will all play critical roles in the EP/COOPs implementation.

Strategic Coordination and Communication: The AVCRA is responsible for providing strategic decision-making for all elements of UNMC HRPP EP/COOP operations. They will communicate with UNMC/NM incident command; coordinate communications with ORA and representatives of components of the HRPP, and principal investigators (PIs); and coordinate the release of information with UNMC Strategic Communications.

- If the AVCRA is unable to fulfil this responsibility, the Assistant Director of the ORA will take over

those responsibilities. They will be aided by (or as necessary, replaced by) the Executive Chair or one of the senior IRB Chairs, as determined by the IO and/or the Vice-Chancellor for Research (VCR).

Research Stoppage: The IO, in consultation with the VCR and the AVCRA, is responsible for the final decision-making regarding the stoppage of any and all research activities, including new IRB reviews.

Periodic Evaluation of the Emergency Plan: The AVCRA is responsible for evaluating the UNMC HRPP EP/COOP and making changes, when appropriate. This evaluation shall occur at least annually.

Periodic Review of the UNMC HRPP EP/COOP Training and Education Plan: The AVCRA is responsible for ensuring the educational materials are reviewed and updated as necessary, based on the outcome of the periodic evaluation of the emergency preparedness plan.

- 1.4. Planning Assumptions

The following assumptions have guided the development of this plan:

The institutions are vulnerable to a full range of hazards (man-made, natural, technological disasters and potentially hazardous materials (area/department dependent) that may constitute an emergency.

An emergency and any resulting impacts may occur during normal business hours and during off hours and may adversely affect the ability of the UNMC HRPP to initiate or sustain its essential functions.

The UNMC AVCRA has authority to implement the UNMC HRPP EP/COOP under emergency conditions affecting UNMC HRPP, even if the institution has not activated incident command or declared an emergency.

Critical personnel and other resources may be requested of the institution by the UNMC AVCRA and will be made available to the extent possible if required to sustain or recover essential functions.

Leadership and all personnel will continue to recognize their responsibilities to public safety and human subjects research protection and will exercise their authority to implement the UNMC HRPP EP/COOP in a timely manner when confronted with emergencies as described above.

All personnel have been trained in the UNMC HRPP EP/COOP and know and understand their role.

---

2. Implementation Procedures

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.

- 2.1. Assess the nature of the risk and the potential impact to the HRPP
  Once an emergency or threat is identified the AVCRA and IO will determine the response based on the nature of the event.
  The AVCRA or IO shall contact the appropriate Institutional personnel [Director of UNMC Office of Emergency Management and Nebraska Medicine Executive Director of Emergency Management and Biopreparedness] to determine whether there are Institutional plans already in place to address the event (as per the institutional COOP plan on file with the UNMC Office of Emergency Management). If these institutional plans are activated, the HRPP will proceed in accordance with those plans and determine whether communication with the research community is necessary to alert them to the activation of the emergency preparedness plan.
- 2.2. Assess and mitigate the impact(s) to HRPP operations
  IRB Meetings: If the emergency may prevent one or more IRB meetings from occurring, the AVCRA will determine whether to cancel or reschedule the meetings after identifying currently approved protocols which may expire prior to IRB review. If research will expire, the ORA will follow UNMC HRPP Policies regarding lapses in approval. If the meeting(s) can be held safely remotely, execute remote IRB meeting procedures.
  If it is expected that IRB meetings will be impacted for a prolonged period of time, arrangements may be made to rely on one or more external IRBs. The AVCRA and IO will determine whether it is in the best interests of the institution and research subjects to make arrangements (contractual or MOU where appropriate) in advance of an emergency to rely upon other organizations or commercial entities for IRB review.
  HRPP Staff protocol processing and review: If staff will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, the AVCRA, Executive IRB chair, and ORA leadership shall work with the staff to prioritize initial reviews, or reviews of Continuing Reviews (CRs), protocol modifications, or other submissions. In general review priority will be based on (1) potential for direct benefit to subjects of the research, (2) number of

subjects impacted, (3) importance of trial to the organization (as determined by the institutional Official) and (4) contractual and/or funding requirements (as more fully described in section 2.4 below).

If research will expire, the ORA/IRB will follow UNMC HRPP Policies regarding lapses in approval.

Data and records: If electronic records are unavailable, the AVCRA thru the COOP coordinator will consult with UNMC Information Technology (IT) support to implement alternative procedures to access backup data and/or email. If access to and functionality of RSS cannot be promptly restored, substitution of PDF forms and/or use of paper forms will be instituted.

The ORA will maintain PDFs of application and other forms on cloud platforms and local hard drives, and paper forms on site.

Use of RR-IRB: Review of new submissions, or significant changes in existing research which cannot be accomplished through regulatory flexibility or protocol modifications as described above, may be accomplished through use of the Rapid Response IRB (IRB-03).

- 2.3. Assess and mitigate the impact on on-going research

  General approach for on-going research

  Based on the nature and severity of the emergency, and the effects on the IRB/ORA operations and research infrastructure, modifications in on-going research protocols may be necessary to accommodate various situations. These situations include (but not limited to) decreased availability of research staff, closure of research space, closure or decreased availability of clinical space (impacting administration of research interventions, data collection and/or safety evaluation), decreased availability of the research intervention (for example, investigational or other products), reduced ability of research participants to travel to research site.

  Options include:
  - Continued enrollment but with protocol modifications (including modification of research plan and/or informed consent process)
  - Restriction of all or some further subject enrollment
    - with continuation of research interventions and data collection for currently enrolled subjects
    - with discontinuation of further research interventions but continuation of data collection for currently enrolled subjects
    - discontinuation of all research interventions and data collection on currently enrolled subjects

  At the beginning of an emergency, the AVCRA, in consultation with appropriate institutional stakeholders, may categorize on-going research protocols in order pre-identify appropriate mitigation actions should the emergency progress and enrollment or study halts become necessary.

  Studies may be broadly assigned to one of several categories.

  Within each category, consideration will be made based on the risk to the individual subject (for example, risks associated with traveling) and, in the case of an infectious disease bioemergency, the risk of spread of infection to others (based on face-to-face contact with investigator or other subjects).

  - *Category 1* – High direct benefit and/or potential for harm to subjects if stopped.
    Protocols in which serious or immediate harm could be caused to the research participants if stopped. This category might include (1) research protocols involving treatments for acute, life-threatening health conditions (for example, some treatment trials for cancers), or (2) protocols where stopping the intervention (for example, some investigational drugs or vaccines or preventative drug regimens) could be harmful.
  - *Category 2* – Moderate direct benefit and/or potential for harm to subjects or scientific value if stopped.
    Protocols which, if stopped, may pose a risk to the research participant, or may cause significant harm to the scientific value of the study. This category might include (1) protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation, (for example, where research test results coming back that might have clinical implications for their care), or (2) some protocols evaluating treatments for chronic conditions, or (3) protocols with less than high direct benefit to subject but where, if stopped or delayed, the potential societal benefit of the science would be significantly and adversely impacted (for example, research where an assessment is only valuable if collected at a very specific time).
  - *Category 3* – Low or no direct benefit to research participants OR low or no direct benefit to research participants and vulnerable subject population OR delays have limited impact on scientific objectives.
    This category might include (1) research with healthy volunteers, or (2) protocols with low or no direct benefit which involve research participants at higher risk for adverse outcome based on the nature of the emergency (for example, persons at higher risk for poor outcomes associated with an infectious disease bioemergency), or (3) cohort and natural history studies where delays in data collection have limited impact on scientific objectives, or where endpoints could be shifted to compensation for delay.

  In addition, in the case of an infectious disease bioemergency, research may also fall into a fourth category:
  - *Category 0* – No face-to face contact with investigators by research subjects.
    This category might include (1) medical records research with waiver of consent, or (2) HBM research w/ waiver of consent, or with sole consent by clinician obtaining tissue for clinical purposes, or (3) Internet based research w/o face-to-face contact.

Specific strategies:

Deviations and Modifications to Existing Research:

The AVCRA, in consultation with the IO as appropriate, may allow investigators to implement procedures to minimize burden on subjects and/or maintain research integrity without modification to the IRB application or formal IRB approval.

- Specifically, the IO and AVCRA may allow minor changes to the study (such as to decrease number of study visits, or to give a "window" for a visit) to proceed without IRB review and approval, provided such changes are temporary and do not increase the risk of harm to participants or adversely impact the data. Such changes would be reported to the IRB until the time of continuing review.
- Major changes to the study (for example, changes in method or dose timing of agent administered, major changes in data collection which affect primary endpoints of the research) would continue to be submitted as separate protocol deviations and reviewed and approved before implementation.
- As always, changes necessary to eliminate apparent immediate hazards to the subject may be made without prior approval of the IRB (per 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(4) and HRPP Policy 2.4).

In-person interactions with research subjects: If studies involve in-person interactions with research subjects, investigators (in consultation with the ORA) will determine whether the studies may be conducted as written, or whether interactions need to be altered to adhere with emergency mitigation strategies.

- If in-person interactions cannot be accommodated, the investigator will need to advise the ORA whether the research can safely continue in a manner which allows for protection of subjects and staff and generates scientifically valid data.

In a manner similar to the way they perform scientific review of clinical research, Departments and/or Colleges should consider conducting a risk-analysis regarding the impact of emergencies on their planned research, and an emergency mitigation strategy for ensuring the safety of research participants.

Safety monitoring: If trial participants are unable to come to the investigational site for protocol specified visits, alternative methods for safety assessments must be considered. This may include utilizing phone contact, virtual/telehealth visits , alternative locations for assessment (including alternate laboratory sites, study visit sites, or imaging centers) to assure the safety of research study participants.

Sponsored research: When studies have an external sponsor, each PI must coordinate with the sponsor to confirm mitigation plans. The PI and study team must document any mitigation strategies that are implemented.

Clinical care and/or research facility considerations: If the emergency impacts clinical care standards which may in turn impact research, the PI must consult with the ORA regarding any changes to protocol activities, and document which do and do not require IRB review. Emergency response plans must be considered for each existing research location and any changes to research locations.

Regulatory Flexibility: When studies are not subject to the Common Rule or to FDA regulations, the ORA may employ "equivalent protections" in protecting the rights and welfare of research participants. For example, the IRB may consider extending continuing review dates during the emergency and allowing more widespread use of waivers of documentation of consent.

Halting existing research: The AVCRA and IO, in consultation with the VCR may consider halting enrollment of new subjects into active research, and/or stopping some or all study activities, for some or all active protocols. As noted above, specific criteria for halting research will be determined based on the nature of the emergency and its expected effect on IRB, ORA and clinical research infrastructure.

- 2.4. Assess and mitigate impact on future research

During the emergency, the IO, in consultation the AVCRA and the VCR, institutional stakeholders, may consider limiting acceptance for review of new protocols submitted to the IRB, based on the nature of the emergency and its expected effect on IRB, ORA and clinical research infrastructure.

If limiting acceptance is deemed necessary, priority for review will be based (in order of importance) on:

(1) potential for direct benefit to subjects of the research

(2) impact of protocol on research and clinical infrastructure

(3) number of potential subjects impacted

(4) Importance of trial to the organization as determined by the IO; and

(5) contractual and/or funding requirements.

Research which is directly related to the operations or understanding of the emergency will also have priority.

As noted above, the AVCRA will have the authority to utilize the Rapid Response IRB, or any other institutional IRB, to conduct reviews of high priority studies. The IO shall have the authority to allow the use of external IRBs as needed to conduct reviews of high priority studies.

- 2.5. Conduct an After-Action Review upon completion of the emergency

Following any emergency, the AVCRA will convene a team to collect information on critical issues requiring leadership attention, lessons learned, and best practices associated with the response. The review will focus on what did and did not facilitate response efforts and the findings will be used to develop recommendations to improve procedures for future event response operations.

The After-Action Review will be shared with the IO, appropriate stakeholders, and the UNMC Office of Emergency Management for inclusion in the overall incident file. Once developed, new or updated procedures should be evaluated for effectiveness in an exercise and any formal updates should be included in the amended UNMC HRPP EP/COOP document.

3. Plan maintenance

The AVCRA will periodically review 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.

4. 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.

DOCUMENT HISTORY:

Written: 8/14/2023 (Approved: 9/1/2023) - {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}