OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #110.0 Revision 0	**TITLE: Emergency Preparedness and Response Plan**	Effective Date: 9/7/2023
Approved By: ORIC Director	Signature 	Date 9/7/2023
Approved By: IRB Chair	Signature 	Date 9/7/2023

PURPOSE

To describe policies and procedures for how the UNM Human Research Protections Program (HRPP) responds to an emergency impacting operations. For this policy, the HRPP includes only the UNM Main Campus Institutional Review Board, Conflict of Interest and Office of Sponsored Projects programs. Other programs, such as biosafety and radiation safety, will follow emergency response procedures as dictated by campus specific requirements.

REVISIONS FROM PREVIOUS VERSION

None

POLICY

This policy establishes written procedures for initiating a response to an emergency impacting the UNM IRB and/or HRPP operations. An emergency may include but is not limited to natural disasters, extreme weather events, man-made disasters, and public health crises. Both the scope and nature of the emergency will be considered when initiating a response. This policy is limited in scope due to the minimal risk nature of the research conducted at UNM.

This SOP establishes HRPP-specific emergency planning and is intended to supplement, not replace, emergency response planning by UNM leadership and/or institution-wide response measures. HRPP-specific emergency response planning and measures are limited only to those functions of the HRPP not otherwise covered by institution-level plans.

This SOP is invoked once the Institutional Official (IO) has indicated an emergency has occurred or preparations are needed for an imminent emergency, and human research overseen by UNM IRB has been or is likely to be adversely impacted.

RESPONSIBILITIES

Execution of SOP: IRB Director, Staff, Members, IO

PROCEDURE

- Assess the nature of the risk and the potential impact to the HRPP.
  - Once an emergency or imminent emergency is identified, determine the response based on the nature of the event.
  - The IRB Director (or designee) shall contact the IO to determine whether there are University Emergency Disaster/Recovery Plans and/or Business Resumptions Plans already in place to address the event. If the IO is unavailable, the Associate Vice President for Research (AVPR) will be contacted. If University-wide plans are activated, proceed in

accordance with those plans and determine whether and how communication with the human research community should commence.
    - Communication will be initiated and directed by the IRB Director (or designee) using the IRB listserv for email communications and the IRB website for broader communication. If these systems are unavailable, alternative modes of communication (such as mass text messaging, mailings, etc.) will be used.
- Assess whether the emergency may impact/has impacted IRB operations.
    - IRB Meetings: If the emergency may prevent one or more IRB meetings from occurring, determine whether to cancel or reschedule the meetings to the earliest possible next date, being certain to identify currently approved human research that may expire prior to IRB review. If research will expire, follow SOP 408 Expiration of IRB Approval regarding lapses in continuing review. UNM IRB will implement alternative review procedures, including leveraging if possible alternative online and virtual platforms, to ensure that IRB meetings can continue.
    - Staff processing and review: If staff will be unable to complete submission processing and review responsibilities, or if capacity will be limited, the IRB Director (or designee) shall work with the staff to prioritize reviews. If research will expire, follow SOP 408 Expiration of IRB Approval regarding lapses in continuing review.
    - Data and records: If data/electronic records are unavailable during the current or anticipated emergency/disaster, consult with local IT support and/or the vendor of the IRB's electronic system to implement alternative procedures to access data/backup data. UNM's eRA vendor has a disaster recovery plan that provides remediation for issues that affect clients.
    - Manual processing: If the electronic records administration system is unavailable, IRB staff will accept and review urgent submissions via alternative methods, such as email or hard copy.
- Assess whether the emergency could impact a researchers' ability to conduct research.
    - Notify the research community via listserv email or website announcement of the potential need for modifications to their current IRB approved research, if appropriate. Some of these changes may include:
        - Alternative methods for in-person study visits/safety monitoring (telemedicine, home visit, alternative location for specific assessments or labs)
        - Shipping investigational products directly to research participants (requires consult with Sponsor and FDA)
        - Implementing remote monitoring processes/programs in lieu of on-site monitoring
    - Develop additional guidance, as necessary: for example, if the emergency impacts clinical care standards which may in turn impact research, clarify what does and does not require IRB review (e.g., screening procedures implemented by the site where a clinical trial is being conducted would not require IRB review/approval of the screening procedures).
    - Consider the types of research that may continue and the types of research that may need to be temporarily suspended or postponed; this consideration may include studies that present a likelihood of direct benefit to participants (or conversely, studies that include study interventions that may be harmful to subjects if discontinued); and research involving direct interactions or interventions but can continue those interventions via alternate mechanisms (such as remote visits).
- Provide education and communication on expectations during an emergency

- Communications and education shall be developed and distributed based on roles/responsibilities within the HRPP. Specifically, researchers and research staff, IRB Chair /IRB members and IRB Staff may each have differing needs with respect to effectively responding to emergency mitigation strategies.
- IRB members and staff will receive education via new member/staff orientation and IRB or staff meetings.
- Communications to researchers and research staff shall occur via standard communication routes, such as email, IRB website and web-based platforms, if available. If the standard routes are not available, the IRB Director (or designee) and IO will determine alternate route(s).
- Any necessary communications to Sponsor will be initiated by the Office of Sponsored Projects or Contract and Grant Accounting, as appropriate.

- The emergency response plan will be evaluated during the bi-annual HRPP review process. If necessary, additional improvements shall be implemented.