Chapter 19

Emergency Preparedness

These guidelines do not replace or supersede the Prisma Health Emergency Management and Preparedness Plan. This info is available at on the Prisma Health Website:

https://connect.prismahealth.org/departments-and-locations/departments/emergency-management-and-preparedness

Realizing that emergencies and disasters may vary in significance, scope and impact, this policy addresses general expectations and strategies to manage impact on the HRPP, IRB processes, and on-going protection of human subjects in research at Prisma Health.

Disasters may be without warning or may allow advance notification. These emergencies may be natural disasters, manmade disasters, public health emergencies, or terrorist actions. The key components of any emergency management plan are Advance Preparation, Communication, and Recovery.

This policy will address preparedness, communication, and continuance of processes during an emergency, and recovery.

1. ADVANCE PREPARATION

a. It is critical that each person have a personal preparedness plan, particularly in situations where there may be the need for mandated evacuations.
b. Requirements of the HRPP Team, IRB coordinators, and IRB committee members will be shared through initial and ongoing education updates.
c. Information and education as they relate to initiation, continuation, and modification to current research will be provided to investigators and study teams with updates on an annual basis as part of HRPP education series.
d. Students should contact Student Affairs Administration for Emergency Procedure requirements of students.

2. PROCESS PREPARATION

HRPP Program/Institutional Review Board

a. The IRB team will maintain lists of all active studies, available for access outside of the protocol management system with contact information for all clinical trials.
b. The IRB will maintain an emergency committee with availability for the purposes of reviewing modifications to current active research to address continued protection of the human subjects enrolled. This committee will have the capacity to meet virtually on an "on call" basis.
c. The IRB will publish contact information for the HRPP Director and IRB Chairs for the purposes of consult, or to address immediate needs of study participants.
d. The HRPP will establish resources with external, commercial IRBs to identify resources available through existing Master Reliance Agreements if the Prisma Health IRB is unable to continue its oversight of existing research and cannot access appropriate resources to review and approve new studies that may be necessary to implement during any local/regional emergency.
e. The IRB staff has the ability and tools and to work remotely and there are resources and platforms for virtual committee members. When electronic virtual resources are not available, telephone communication will be used if necessary for the conduct of meetings in an emergency.
f. All required regulations and processes will be followed for these emergency meetings, including an appropriate quorum and committee member requirements.

Investigators and Study Teams

a. Investigators and study teams should update study participants' emergency contact numbers and emails annually and maintain this list as accessible if needed to print and have available for use outside of the organization.
b. Investigators and study teams should assure that they have appropriate contact information for essential personal in Research Services, particularly the IRB.
c. Plans should be established with the research pharmacy to assure that they are aware of the pharmacy policies in emergency situations.
d. Listings of current protocols with sponsor and CRO contacts should be developed and maintained current.

Management of Research During an Emergency

a. In collaboration with the Vice President for Research Compliance and Administration, Administrative and Medical Leadership, determinations will be made, based on the presenting situations to curtail implementation of new studies and/or continue existing studies.
b. Established projects being conducted in partnership with the organization's university partners will be evaluated with the Research Directors for those programs and assessed based on and in coordination with the university emergency response requirements.
c. The Vice President for Research Compliance and Administration will schedule huddles of key personnel for ongoing assessment of response requirements.
d. The Prisma Health HRPP policies and SOPs may be modified as appropriate for the situation. Such modification may include alternative meeting procedures, alternative procedures for the submission and review of modifications, alternative procedures for prompt reporting, and any other changes necessary to ensure appropriate ongoing oversight and conduct of research.
e. Because procedural modifications may vary based on the nature of the event, these cannot be anticipated or described prospectively. Such procedural modifications will be recorded in an addendum to the SOPs, note-to-file, or other appropriate means of documentation and communicated to the research community through available technology.
f. As available, the HRPP website will be the mechanism utilized for communication.

Recovery Period

Following the resolution of the event, study teams should review:

a. All current, active patients and determine if there were deviations to treatment or follow-up requirements.
b. Identify any serious adverse events that require reporting that may have occurred during the emergency period when some services may have been suspended.
c. Identify any protocol modifications that may be required to address on-going issues following the emergency identified either locally or by the study sponsor and submit to the IRB for review and determination.

Following the resolution of the event, the IRB team should review:

a. Ongoing statuses of studies that may have been suspended.
b. All actions/determination made during the event to assure there is

appropriate documentation of review.

c. Contact study teams to assist or determine with on-going requirements that may be in place as the organization ramps back up.
d. Conduct a situation de-brief with thirty days of resolution of the event to assess program performance and effectiveness of the emergency management plan and adjust plan as needed.