IRB Emergency Preparedness Plan (EPP)

Purpose

- Serves as an information source for those within the human research protection community in the event of an emergency
  - MUSC IRB staff, IRB Chairs and members, MUSC investigators, etc.
- Plan does not replace emergency response plans put in place by MUSC institutional leadership
  - Supplement to institutional emergency response plans and will activate when plans are needed for an imminent emergency where human subjects research is or is likely to be adversely impacted
- An emergency may include (but is not limited to):
  - Natural disasters
  - Cyber-attack
  - Man-made disasters
  - Extreme weather events
  - Public Health crises

Scope

- The EPP includes:
  - Research conducted at MUSC main campuses
  - Research sites for which MUSC is the IRB of record
- The EPP covers:
  - Anyone associated with the review and processing of applications (HRPP Staff)
  - Anyone that supports or is engaged in the conduct of human subject's research at MUSC IRB or any external site for which MUSC is the IRB of record

Responsibilities

- Researchers
  - Should consider the need for an emergency response plan for their ongoing, approved research
    - A plan may not be needed if:
      - The research does not involve in-person interactions or
      - The research can be conducted as approved by the IRB while adhering to institutional requirements
  - Responsible for contacting the sponsor (if applicable) to determine if the sponsor has an emergency response plan in place
    - Any institutional requirements that are more restrictive than a sponsor's emergency response plan must be followed
- IRB
  - ORI Director (or his/her designee) is responsible for activating and carrying out the procedures
    - Will be based on the scale/type of emergency and its potential impact on the functionality of the IRB

Notification

- Research Community
  - Sent out via Vice President for Research listserv (VPR listserv)
    - Researchers and Research Staff are responsible for communicating with their research participants what actions are necessary to either maintain or discontinue their involvement in the research during the emergency
- IRB Staff and Board Members
  - Sent via standard methods (emails, phone calls, text messages, and/or MUSC websites)
- When the emergency no longer presents a limitation to the IRB Office functions, the ORI Director and manager will work with the Institution's leadership to notify the IRB Board Members, Staff and the research community that normal business operations have resumed.

Disruption- IRB Meetings

- Location
  - Held remotely via Microsoft TEAMS
    - Anticipated that IRB meetings will be able to continue even if members must shelter in place as long as communication capabilities are available
  - If TEAMS is not an option, teleconference may be used as an alternative
- Voting
  - Alternate members may substitute for IRB members who are unable to attend a meeting and may vote for an identified primary member in the primary member's absence (HRPP 2.3)
- Quorum
  - During an ongoing emergency, if quorum can't be maintained:
    - ORI Director/IRB Manager will assess options for transferring IRB oversight to an AAHRPP accredited IRB that may serve as an alternative to an internal IRB review process
      - Includes reliance on commercial IRBs and institutions that are members of the SMART IRB initiative
    - MUSC IRB will work with these IRBs to execute the transfer of oversight
    - When MUSC IRB functions resume, studies with deferred IRB oversight will be transferred back to the MUSC IRB

Disruption - Research

- Short of stopping all research during an emergency, identify the following types of studies:
  - Studies which should be halted entirely or partially
    - Criteria:
      - Continuing research interventions/interactions will adversely impact risks for participants
      - Continuing the study will have an adverse impact on resources required to address the emergency
  - Studies for which recruitment or enrollment should be halted but all or some research activities may continue for existing participants
  - Studies that can continue to enroll new participants via alternate mechanisms
    - Criteria:
      - The study presents a likelihood of direct benefit to participant
      - The study requires continued assessment and monitoring for safety issues
      - The study involves direct interaction or intervention, but procedures can continue with risk minimization by conducting study procedures via alternate mechanisms (Ex. use of remote study visits, conference calls, or video conferencing)
  - Studies which could use waivers of documentation of consent
    - For most minimal risk research that involves interaction with participants, to prevent the need to notify participants of changes to consent documents
    - Exempt/ Expedited Reviews- The current process for exempt and expedited reviews will continue with available Board members and IRB staff

Disruption - eIRB

- Research Administration has developed response plans for all information technology systems necessary to operate the IRB and includes:
    - Security, support and back up required to maintain the integrity and access to the system
- In the event that the eIRB system is not accessible during an emergency
    - IRB Staff can share review materials with IRB members via email
    - Study teams may communicate study-related materials to the MUSC IRB through email
        - Can upload documents into eIRB once service to the system is restored

What questions do you have?