EMERGENCY PREPAREDNESS PLAN (EPP)

MUSC IRB 2026

MUSC
Medical University of South Carolina

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, IRB members, MUSC investigators, etc.

- Plan **does not** replace emergency response plans put in place by MUSC institutional leadership
    - Supplement to institutional emergency response plans.
    - Activates 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 disaster - Cyber attack - Man made disaster - Extreme weather events-

-Public health crisis-

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/is engaged in the conduct of human subject research at MUSC IRB.
- Any external site for which MUSC is the IRB of record.

RESPONSIBILTIES

Emergency Response Plan

Consider the need for an emergency response plan for ongoing, approved research.

Response Plan Needed:?

A response plan may not be needed if:

- The research does not involve in-person interactions.
- The research can be conducted as IRB approved while adhering to institutional requirements.

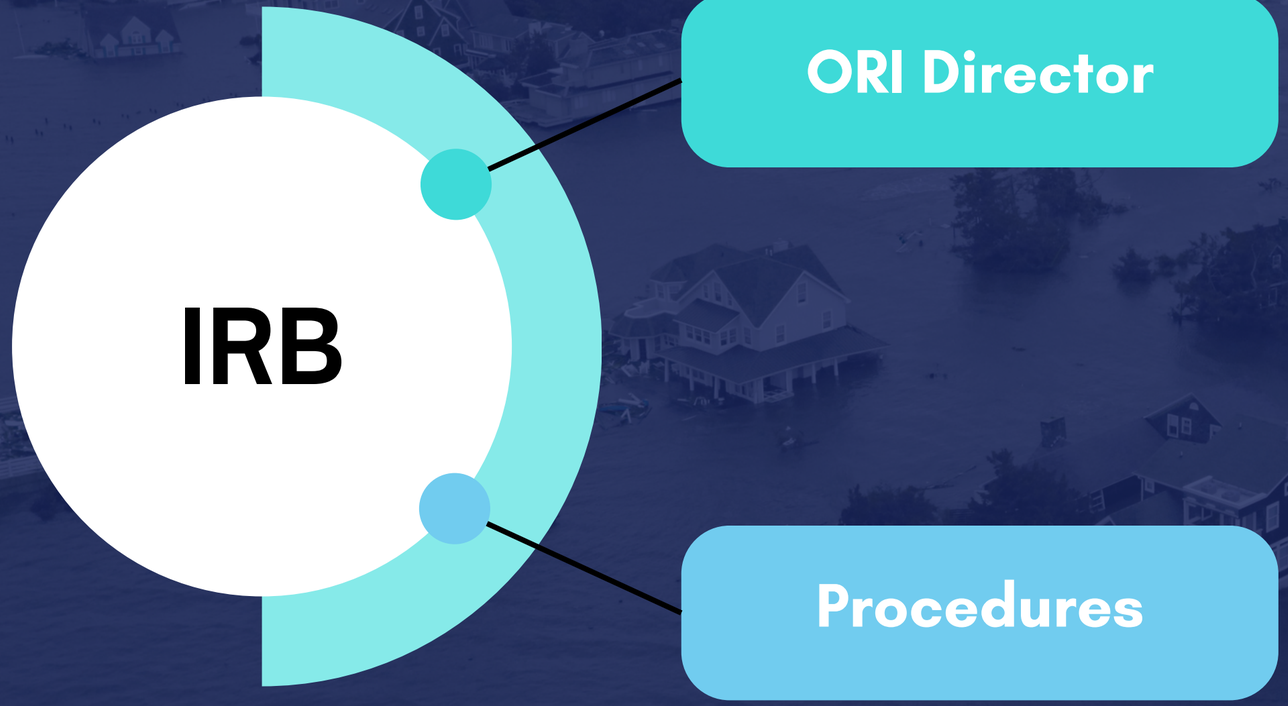
Sponsor Contact

Responsible for contacting the sponsor (if applicable) to determine if the sponsor has an emergency response plan in place.

Insitutional Requirements

Any insitutional requirements that are more restrictive than a sponsor's emergency response plan must be followed.

RESPONSIBILTIES



- Responsible for activating and carrying out these procedures dependent on the potential damage to IRB operations.
- Collaborates with institutional leadership to identify what types of research may continue and what types can temporarily be placed on hold.

Will be based on the scale/type of emergency and it's potential impact on the functionality of the IRB.

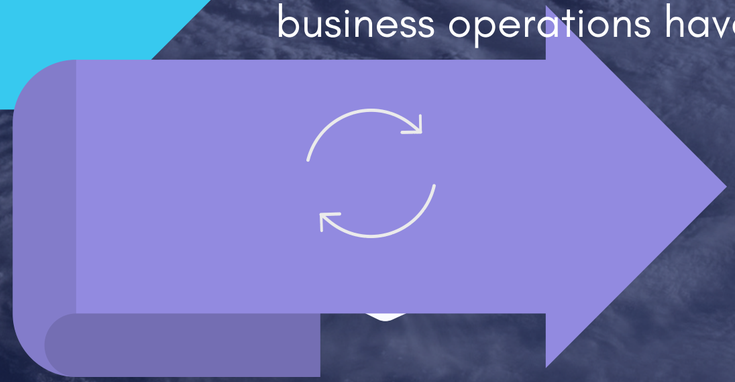
NOTIFICATION

Research Community

- Sent out via Vice President for Research listserv (VPR listserv).
- Researchers/Research staff responsible for communicating with their research participants what actions are necessary to either maintain or discontinue their involvement in the research during the emeregency.

IRB Staff and Board Members

- Sent via standard methods (email, phone calls, text message, and/or MUSC websites).



End of Emergency

- When the emergency no longer presents a limitation to the IRB office functions, the ORI Director & manager will work with the Insitution's leadership to notify the IRB board members, staff, and research community that normal business operations have resumed.

DISRUPTION

IRB Meetings

Remote

Voting

Quorum

01

- Held remotely via MS Teams.
- Anticipated that IRB meetings will be able to continue even if members must shelter in place as long as communication capabilities are available.

02

- Alternate members may substitute for IRB members who are unable to attend and may vote for an identified primary member in the primary member's absence (HRPP 2.3).

03

If quorum cannot be maintained:

- ORI Director/IRB manager will assess options for transferring IRB oversight to an AAHRPP accredited IRB.
- Includes reliance on commerical IRB's and insitutions that are members of the SMART IRB initiative.
- When MUSC IRB functions resume, studies with deferred IRB oversight will be transferred back to MUSC IRB.

DISRUPTION - RESEARCH

SHORT OF STOPPING ALL RESEARCH DURING AN EMERGENCY, IDENTIFY THE FOLLOWING TYPES OF STUDIES:

Studies which should be halted entirely/partially:

Criteria:

- Continuing research interventions/interactions will adversely impact participant risks.
- Continuing the study will have an adverse impact on emergency resources.

Studies for which recruitment/enrollment should be halted but all/some research activities may continue for existing participants.

Studies that can continue to enroll via alternate mechanisms:

Criteria:

- Study presents a likelihood of direct benefit to participant.
- Study requires continued assessment & monitoring for safety issues.
- Study involves direct interaction / intervention, but procedures can be conducted via alternate mechanisms.

Studies which could use waivers of documentation of consent:

- Most minimal risk research that involves interaction with participants, to prevent the need to notify participants of changes to consent documents.

Exempt/Expedited Reviews

- Current process for exempt & expedited reviews will continue with available board members/IRB staff.

DISRUPTION EIRB

IT SYSTEM RESPONSE PLANS

- Security, support & backup required to maintain integrity and access to system.

IN THE EVENT EIRB NOT ACCESSIBLE:

IRB STAFF

Share review matierals via email.

STUDY TEAMS

Communicate study-related materials via email.

EIRB RESTORED

Upload materials in eIRB once service to system is restored.

Questions