

Institutional Review Board (IRB) Emergency Preparedness Plan (EPP)

PURPOSE:

The MUSC Institutional Review Board (IRB) Emergency Preparedness Plan (EPP) establishes procedures for initiating a response to an emergency that impacts the operation of the MUSC IRB. This policy will be used as an information source for the MUSC IRB staff, IRB Chairs and members, as well as MUSC investigators and others within the human research protection community in the event of an emergency. This plan does not replace emergency response planning put in place by MUSC institutional leadership. The EPP is used as a supplement to the institution's emergency response plan and will activate when preparations are needed for an imminent emergency where human subjects research is or is likely to be adversely impacted. These IRB-specific emergency response plans and measures are limited only to those functions of the IRB not otherwise covered by institution-level plans. Any additional requirements and instructions for research investigators and research participants will be coordinated with the relevant institutional emergency preparedness or response plan.

An emergency may include, but is not limited to natural disasters, , cyber-attack, man-made disasters, extreme weather events and public health crises.

SCOPE

The EPP is intended to include research conducted at MUSC main campuses as well as research sites for which the MUSC IRB is the IRB with oversight authority. The EPP is meant to cover HRPP staff, including anyone associated with the review and processing of applications, IRB members, and anyone that supports or is engaged in the conduct of human subject research at MUSC IRB or any external site for which the MUSC IRB is the reviewing IRB.

EDUCATION:

HRPP leadership will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. IRB Staff and Board Members will be educated and trained on the EPP annually via Continuing Education. New Board Members and Staff will be trained via educational presentation as part of onboarding. Researchers and research staff will receive education and training via the quarterly MUSC IRB Newsletter.

The HRPP emergency preparedness plan will be made available to the human research community via the IRB website for continuous review by staff and members.

NOTIFICATION:

In the event the emergency plan needs to be implemented, communications to the research community will be sent out via the Vice President for Research listserv (VPR listserv) to inform Researchers of any additional measures the IRB will take to maximize regulatory flexibility during an emergency.

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 an emergency.

IRB Staff and Board Members will be notified that the EPP has been activated via standard methods such as emails, phone calls, text messages, and/or MUSC websites.

UNIVERSITY RESPONSIBILITIES

The MUSC enterprise has an emergency operations plan that addresses concerns related to campus and personnel safety and information technology infrastructure. This plan is reassessed as needed by Institutional leadership. The highest risk threats and hazards are identified in the University Emergency Management Guidelines.

RESEARCHER RESPONSIBILITIES:

Researchers should consider the need for an emergency response plan for their ongoing, approved research studies. Emergencies can lead to difficulty with conducting study procedures, safety monitoring, communications with participants and access to and use of investigational drugs and devices. 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 regarding the emergency. When studies have an external sponsor, the researcher must contact the sponsor to determine if they have an emergency response plan in place. Any institutional requirements that are more restrictive than a sponsor's emergency response plan must be followed. Researchers must be knowledgeable that when planning to conduct research during emergencies, they should obtain IRB approval in advance where possible.

IRB Recommendations to all Principal Investigators and Study Staff

1. Emergency contact procedure should be developed and disseminated to study staff and a copy kept on file in the regulatory binder. Items to include in this plan:
 - a. Where you will relocate your facility.
 - b. Notifying subjects of the trial.
 - c. If there is a sponsor, notifying the sponsor and receiving approval.
 - d. Contact List for Personnel

2. Discuss with Sponsors their requirements should a disaster occur and update sponsor contact information.
3. Subject rosters should be created before an emergency and the PI should provide the subject roster to appropriate study personnel with the following information:
 - a. Name
 - b. Address
 - c. Phone (land and cell)
 - d. Email
 - e. Other Contact Method
 - f. Study in which Subject is Participating
 - g. Trial personnel rosters with contact information should be created and distributed to all trial personnel.
 - h. Emergency contact wallet card should be created and provided to subjects with the following information:
 - i. PI Name and phone number.
 - ii. Coordinator name (and phone number if applicable)
 - iii. Study name and identifying numbers.
 - iv. Study drug and/or device, if known.
 - i. A letter should be provided to those participants in drug or device trials explaining how to contact the research team in case of a disaster.
 - j. Coordinate with Investigational Drug Services and create a Disaster Plan.

Pre and Post Disaster: IRB Recommendations to all Principal Investigators

Once a Disaster Threatens:

1. Meet with subjects and provide additional supplies and medications. Designate a staff member to take calls.
2. Mail specimens, use offsite backup storage of unique materials and samples; inventory samples.
3. Complete and secure study records in plastic bags and labeled boxes, in a limited access area anticipated to remain dry.
4. Safeguard lab books, protocols in progress, proposals, account #'s for active awards, recent budget statements for their accounts, names and contact information for agency program officers.
5. Take copies of critical documentation/data.
6. Ensure that all critical files are backed up on appropriate server.

During and After a Disaster:

1. Maintain communication records for subjects.
2. Contact sponsors to make certain study products are safe for distribution to subjects prior to dispensing.
3. Reestablish the study visit schedule.
4. Report all deviations and unanticipated problems to IRB.

5. If study passes IRB approval expiration date, DO NOT ENROLL NEW SUBJECTS.

IRB RESPONSIBILITIES:

The ORI Director or their designee is responsible for activating and carrying out these procedures dependent on the potential damage to IRB operations. The ORI Director will collaborate with institutional leadership to identify what types of research may continue and what types of research can temporarily be placed on hold. This will be based on the scale/type of the emergency and its potential impact on the IRB functionality.

The Emergency Preparedness Plan (EPP) will be evaluated annually. The ORI Director, or their designee, will complete the evaluation. Changes will be made as needed.

IRB Logistics

Contact Information

1. IRB Central Phone Line will provide a source of communication among the research community and to allow a central means of contact for the Board members and IRB staff, a central call-in telephone number will be available. This line will be used:
 - a. To disseminate communication to the research community from the IRB.
 - b. To hold IRB meetings during times of disaster (if needed)
 - c. As communication tool for the research community to contact key personnel in the IRB during a disaster situation.
2. To facilitate communication post-event, all individuals with research operations should access the Vice President for Research link on the MUSC Emergency Web site as soon as possible post-event, this site will provide updates on any damages and actions being taken to address damages and preserve research materials. MUSC site: [Disaster Preparedness Policy | MUSC Research](#) or [Alerts & Notifications | MUSC](#)

Procedures:

If an emergency has occurred, or there is an imminent possibility of an upcoming emergency, the nature of the event and the appropriate response will be assessed, and the Institution's Emergency Preparedness Plan will be consulted. If the emergency will impact IRB operations and necessitate additional flexibility, the IRB will work with the institution to notify the research community of the IRB Office's limited capacity to process and review submissions.

An essential function of the MUSC IRB is performing reviews of applications requiring IRB oversight.

Review of Time Sensitive Matters

1. The IRB Chair or designee will be available to complete required expedited and exempt reviews.
2. Full board review will be held as deemed appropriate by the IRB Chair in consultation with the IRB manager and Director.
 - a. The Director of ORI will notify federal agencies about MUSC's research situation if a disaster occurs.

Convened Meeting Postponement During Emergencies

IRB meetings are held remotely via Microsoft TEAMS. As a result, it is anticipated that IRB meetings will be able to continue even if members must shelter in place as long as communication capabilities are available. In the event TEAMS is not an option, teleconference may be used as an alternative to hold IRB meetings.

If access to eIRB is disrupted, review materials could be shared with IRB members via email.

In accordance with HRPP 2.3, alternate members may substitute for IRB members who are unable to attend a meeting. Alternates may vote for an identified primary member in the primary member's absence.

If an emergency is ongoing and IRB quorum cannot be obtained, the ORI Director and 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. This includes reliance on commercial IRBs and institutions that are members of the SMART IRB initiative. The MUSC IRB will work with these IRBs to execute the transfer of oversight. When the MUSC IRB functions resume, studies with deferred IRB oversight will be transferred back to the MUSC IRB. This process will be coordinated between MUSC IRB, the relying institution and the researchers.

When a convened IRB meeting must be postponed due to an emergency, the permissible postponement period is governed by the earliest continuing review deadline among studies with pending agenda items or approaching renewal dates. The IRB Manager, in coordination with the ORI Director and IRB Chair, shall identify this deadline at the time the emergency is declared and use it to determine the appropriate course of action:

1. If the meeting can be rescheduled and held prior to the earliest continuing review deadline, and quorum can be achieved through available primary or alternate members, the meeting may be postponed to that rescheduled date.

2. If the meeting cannot be held prior to the earliest continuing review deadline, the ORI Director and IRB Manager shall initiate formal transfer of oversight of the affected study or studies to an AAHRPP-accredited IRB, including commercial IRBs or institutions participating in the SMART IRB initiative, consistent with existing EPP procedures for oversight transfer.
3. Under no circumstances shall a study's continuing review approval be permitted to lapse as a result of an emergency-related postponement. Lapse of approval is a regulatory violation under 45 CFR 46 and 21 CFR 56 regardless of emergency circumstances. If lapse cannot be avoided, the ORI Director shall consult MUSC legal counsel and notify OHRP and/or FDA as applicable.

Actions to address the impact of the emergency

The nature of each emergency will dictate the specific response taken by the IRB leadership, IRB Chairs and the IO. Leadership will take into consideration whether the nature of the emergency/disaster may pose additional threats or risk to specific aspects of the institutions research activities or facilities.

Limitations on the conduct of human subject research that may occur during emergencies and disasters, short of stopping all research, include identifying:

1. Types of studies which should be halted entirely. The following criteria may be used to identify studies which will be entirely or partially halted:
 - a. Continuing research interventions/interactions will adversely impact risks for participants.
 - b. Continuing the study will have an adverse impact on resources required to address the emergency
2. Types of studies for which recruitment or enrollment should be halted but all or some research activities may continue for existing participants.
3. Types of studies that can continue to enroll new participants via alternate mechanisms, such as the use of remote study visits, conference calls, or video conferencing.

The following criteria may be used to identify studies which may continue:

- The study requires continued assessment and monitoring for safety issues.
- The study presents a likelihood of direct benefit to participant.

- The study involves direct interaction or intervention but procedures can continue with risk minimization by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or video conferencing.
- Types of 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.

Disruptions to eIRB

1. MUSC IRB relies upon eIRB (an online IRB application and management system) and may depend on video conferencing systems entirely to operate during emergency or disaster.
2. Research Administration has developed response plans for all information technology systems necessary to operate the IRB. This includes security, support and back up required to maintain the integrity and access to the system. The plan includes the eIRB application, describes what will be done in an event of an emergency and puts a mechanism in place to secure the system on an ongoing basis.
3. In the event that eIRB is unavailable to users but other office systems are not impacted, study teams may communicate study-related materials to the MUSC IRB through email. Documents may be loaded by study teams into eIRB once service to the system is restored.
4. 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.