



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Emergency Preparedness and Response

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### 1.0 Purpose

To ensure sustainability of MU HRPP/IRB and the continued protection of research participants, as well as assist investigators in protecting the continuity of research during an emergency.

### 2.0 Scope

This SOP should be used as a practical guideline and information source for MU HRPP/IRB staff, board members, as well as MU investigators and department administrators in the event of an emergency. It is not meant to replace the official MU Environmental Health & Safety emergency preparedness information or MU Alert.

In the event of an emergency, these SOPs may be modified as appropriate, as no advance planning can address all possible emergencies. Procedural modifications will be recorded in an addendum to the SOPs, or other appropriate means of documentation communicated to investigators.

### 3.0 Roles/Responsibilities

#### Periodic Evaluation of Emergency Preparedness and Response SOP

It is the responsibility of the MU HRPP/IRB Director and Associate Vice Chancellor for Research (AVCR) to periodically evaluate the Emergency Preparedness and Response SOP to ensure that changes are implemented, as needed.

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### **University of Missouri Emergency Notification:**

All MU faculty, staff and students can register to receive emergency notifications from MU Alert through their accounts on myZou or myHR. More information on MU Alert can be found at <https://mualert.missouri.edu>. MU affiliates or community members can register to receive notifications from MU Alert at <https://mualert.missouri.edu/what-to-do/signup-public>.

- I. HRPP/IRB Staff and Board Members
  - a. MU HRPP/IRB staff and board members may receive additional notification and guidance on implementing emergency preparedness plans from the HRPP/IRB Director or designee in the event of an emergency.
    - i. If the emergency results in closure and/or transition to remote operations, the HRPP/IRB staff will be reminded of the following University of Missouri System policy: [HR-217 Emergency Closure and Transition to Remote Operations](#).
    - ii. Board meetings are held remotely via zoom and will continue to be conducted remotely unless the issue is with remote work, then in-person meetings will occur, if possible. If both are not possible, the plan to utilize another IRB will be implemented until MU board meetings can resume.
- II. Department Administrators
  - a. The AVCR regularly communicates with the MU Associate Deans of Research to discuss emergency preparedness plans for each School on campus. Those plans are periodically discussed and revised as necessary at their monthly meetings. Plans to notify investigators is also discussed during these meetings.
- III. Investigators
  - a. Investigators must inform their research subjects about what to do in the event of an emergency if their participation would be affected by and during an emergency. Documentation of subject contact should be kept in the research files.

### **Emergency Training**

- I. HRPP/IRB Staff:
  - a. The Director will educate and train HRPP/IRB staff on expectations during emergencies on an ongoing basis as necessary. Information in this policy will be covered and other institutional information received that would be helpful if such an emergency occurs.
  - b. IRB Chairs and members will receive information regarding this policy at board meetings and be updated via email or phone calls as necessary if new information arises. Expectations will be communicated again if such an emergency occurs
- II. Investigators:
  - a. Investigators will be educated about expectations during emergencies on an ongoing basis utilizing the RII monthly newsletter and HRPP/IRB monthly seminars. This MU HRPP/IRB policy is also available on its website for access at any time.

#### 4.0 Policies/Procedures

##### **Advance Preparation for MU HRPP/IRB:**

The AVCR and Director of the HRPP/IRB will assess the potential damage to the HRPP, which may vary based on the scale of the emergency. A local emergency, such as an industrial accident, may overwhelm local resources, but the AVCR may be able to obtain assistance from hospitals, universities, or research centers in the region to maintain continuity of operations of the HRPP. In contrast, regional events such as hurricanes or earthquakes mean that a greater number of organizations are impacted and assistance, if available, will be from organizations that are farther away. An infectious disease pandemic impacts all organizations, so there may be limited or no ability to obtain assistance from other organizations.

Actions MU HRPP/IRB may take during emergencies, short of stopping all research, include identifying:

- a. Types of studies the implementation of which should be postponed.
- b. Types of studies for which recruitment or enrollment should be halted but research activities continued on existing participants.
- c. Types of studies that can continue via alternate mechanisms, such as the use of remote study visits, conference calls, or video conferencing.

The following criteria to triage the types of research that might continue and the types that may need to temporarily postpone will include whether the study:

- a. presents a likelihood of direct benefit to participants.
- b. involves interaction or intervention that creates increased risks.
- c. involves direct interaction or intervention but can manage risks by conducting study procedures via alternate mechanisms, including the use of remote study visits, conference calls, or video conferencing, or by canceling in-person gatherings of people involving research activities and holding meetings such as focus groups and research-related activities, such as community advisory boards and participant and support groups for study participants.
- d. will have an adverse impact on resources required to address the emergency.

The MU IRB may exercise additional flexibility in oversight when research is not covered by regulations (for example, unfunded research) by extending continuing review dates, and/or allowing minor changes to be reported after implementation. Major changes may undergo expedited review when full board review would normally have been required. Depending on the nature of the emergency, the flexibility plan will be created and promptly communicated to investigators.

##### **Disruptions to eCompliance and/or Electronic Communications**

MU HRPP/IRB relies upon eCompliance (an online IRB application and management system) and may depend on video conferencing systems entirely to operate during a public health emergency. If MU HRPP/IRB cannot access these systems during an emergency, including cyber threat emergencies, the Director, in consultation with the AVCR, will identify other ways to operate during the public health emergency and notify staff, board members, and investigators.

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The Division of RII IT developed a policy entitled “eCompliance Application at the University of Missouri – Emergency/Disaster Preparedness” which will be followed. It describes the eCompliance application and what will be done in an event of an emergency.

### **Utilizing Another IRB During an Emergency**

In the event it is appropriate to rely upon another organization for IRB review, the MU HRPP/IRB will select another IRB based on:

1. Accreditation Status: The IRB must be accredited.
2. SMART IRB Member: Preference will be given to IRBs part of SMART IRB to negotiate agreements more efficiently.
3. Greater Plains Consortium (GPC) IRBs: Preference will be given to IRBs part of GPC since the IRBs have a good working relationship and meet regularly to discuss GPC activities and other IRB related questions.

MU HRPP/IRB will work directly with the appropriate IRB to discuss arrangements for IRB review and will communicate to MU investigators the process to submit protocols, changes, and other reportable activities requiring IRB review and approval. When MU HRPP/IRB can function, IRB review and approval materials will be transferred to MU IRB via secure methods and updated in eCompliance by IRB staff, with potential assistance from investigators.

### **Advance Preparation for Investigators:**

#### **I. Protocol Development and Scientific Review**

- a. The need for response plans will be based on the type of research conducted and degree of risk in the event a study could not continue. A social, behavioral, or educational study may not require investigators to develop an emergency response plan.
- b. The MU IRB will evaluate whether investigators have emergency response plans in place for their research locations. This will be based on whether the research is conducted at a university or hospital or dedicated research center, or whether the research will be conducted in a physician's office.
- c. Investigators should develop alternate mechanisms for safety monitoring. If trial participants may not be able to come to the investigational site for protocol-specified visits, the IRB will evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible and would be sufficient to assure the safety of trial participants.
- d. Investigators should consider requests for the use of 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.
- e. Investigators must be knowledgeable when planning to conduct research during emergencies, they should obtain IRB review in advance where possible.
- f. If there are organization wide changes that impact clinical care and research in similar ways, these do not require IRB review. Examples of changes that do not

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require IRB review include screening procedures mandated by the health care system in which a clinical trial is being conducted.

### II. Communication Plan

- a. Investigators should collect and update subjects' emergency contact information annually if their health, safety, or welfare could be jeopardized during an emergency. Investigators must still be able to access/retrieve this information under emergency conditions.
- b. Investigators should make sure subjects are aware of alternative methods of contacting research team during an emergency (as necessary).

### II. Pharmacy Plans

- a. For studies involving investigational drugs, investigators need to work with the pharmacy on plans for emergency preparedness. MU Health Care has a policy covering IDS plans in the event of a power outage. This will be followed during power outages.
- b. The IDS Pharmacist will work directly with sponsors in the event of an emergency to ensure adequate supply of drugs for research participants.
- c. IDS is creating an emergency preparedness section within their SOPs.
- d. Sponsors, in consultation with clinical investigators and IRB may determine that the protection of a participant's safety, welfare, and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial. Such decisions will depend on specific circumstances, including the nature of the investigational product, the ability to conduct appropriate safety monitoring, the potential impact on the investigational product supply chain, and the nature of the disease under study in the trial.
- e. FDA Guidance entitled "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency" will be used to set guidelines to ensure the safety of research participants. <https://www.fda.gov/media/136238/download>

### III. Plans for Research Labs and Medical Facilities

- a. Investigators should conduct a risk assessment and identify essential functions that may be impacted in an emergency and develop plans for emergency preparedness. Investigators should work directly with their Associate Deans for Research to develop such plans.
  - ii. Evaluation of chemical, biological, radiologic, and nuclear threats may include risks posed by research labs, as well as external risks posed by industrial accidents and risks posed by terrorist events.
- b. Develop alternate operating procedures in response to emergencies.
- c. Train staff on emergency response procedures and conduct periodic testing of alternate operating procedures.
- d. Maintain updated list of study inventory and equipment.

### IV. Plan for Extended Loss of Power (Electric power or flooding)

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- a. Associate Deans for Research should work with investigators in their area to develop plans for extended loss of power. These plans should include how biospecimen repositories and research databases will be protected.
- V. Modifications to Research
- a. MU HRPP/IRB staff are available for consultation on advance emergency preparedness and response planning. Modifications to research should be approved in advance by the IRB, when possible.
  - b. If unforeseen modifications are required to eliminate hazards or harm to subjects, investigator must report the changes to the IRB as soon as possible and no later than 5 days after the event. If reporting is impossible due to the emergency, investigator must keep records of all changes to report as soon as they are able, or follow other instructions provided by the MU HRPP/IRB since this typical deadline may be extended.

### Reference:

Association for the Accreditation of Human Research Protection Programs (AAHRPP):  
<https://www.aahrpp.org/resources/for-accreditation/tipsheets/emergency-preparedness-and-response>