

WMed Emergency Preparedness and Response Plan



Maureen Owens, CIP
HRPP Director

Domain I.1.H AAHRPP Standards

Requires accredited organizations to have and follow “written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.” The Element includes four essential requirements:

1. The HRPP has an emergency preparedness plan
2. The plan is periodically evaluated
3. Education is provided about the emergency response plan for IRB members, staff, researchers, and other members of the HRPP
4. Persons in the HRPP are knowledgeable about the organization’s expectations during emergencies

Objectives

How would we respond?

What process would we follow?

What is your role?

What was the response when the pandemic hit?

Response Plan

Depending on the nature of the event, the HRPP Director would collaborate with institutional leadership (IO, IRB Chair, Clinical Trials Manager, affiliates, incident command) to determine what types of research may continue and the types that may need to be temporarily postponed.

- We have also identified external IRBs on which we could rely on a temporarily basis if needed.

The organization would implement alternative review procedures, including leveraging virtual platforms like Teams to ensure IRB meetings could continue in scenarios where the IRB cannot meet in person.

- In instances where the convened IRB is unable to meet and IRB approval for a study may lapse, the IRB Chair(s) would determine whether subjects can continue to participate in research activities. For example, if continuing was in the best interest (direct benefit) of already enrolled subjects.

Response Process

Emergency disaster situation occurs (*extreme weather event, natural disaster infectious disease outbreak, etc.*) requiring response. Defer to response communicated by the command incident center (FAC25 Internal Emergency Management Plan).

Address any areas of operation not otherwise covered by the institutional-level plans as follows:

1. Decide whether scheduled IRB meeting could be held virtually or should be cancelled / rescheduled. If currently approved Human Research has or will expire prior to IRB review due to the cancellation / rescheduling, treat as expiration of IRB Approval.
2. If IRB staff will be unable to complete their protocol processing and review responsibilities during the emergency/disaster, or if capacity will be limited for a period, work with the staff to prioritize protocol processing, pre-review, and review of continuing review submissions. If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations, treat as expiration of IRB Approval.

Response Process, Cont'd

Address any areas of operation not otherwise covered by the institutional-level plans as follows, Cont'd:

3. Notify the research community of the IRB Office's limited capacity to process and review submissions. When the emergency/disaster no longer presents a limitation to IRB Office functions, notify the IRB members and staff and research community that normal business operations have resumed.
4. If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.
5. If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with local IT support and or electronic system vendors to implement alternative procedures to access data/backup data.

Response Process, Cont'd

Assess whether the emergency/disaster could necessitate additional flexibility in IRB review processes. If yes,:

- Review additional considerations with the IRB Chair(s) and staff in advance of upcoming IRB meetings.
- Communicate to IRB Members (including Designated Reviewers performing non-committee reviews) that the additional considerations may be incorporated into IRB reviews where appropriate to maximize regulatory flexibility while continuing to assure research subject safety during the emergency/disaster.
- Determine whether additional communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster and notify the community as appropriate.

Response Process, Cont'd

Assess whether the emergency/disaster could impact some or all investigators' ability to conduct Human Research. If yes,:

- Notify the research community of the need for protocol-specific emergency/disaster risk mitigation planning.
- Provide investigators with guidance as needed. If the emergency/disaster could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarify what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).
- When the emergency/disaster no longer presents a limitation to Human Research activities, notify the research community that normal business operations have resumed.

Response Process, Cont'd

Evaluate whether the nature of the emergency/disaster may pose additional threats or risk to specific aspects of the institutions research activities or facilities.

For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some chemical, biological, or radiologic facilities to a greater extent than other facilities. If yes, and if broader institution-level emergency/disaster preparedness measures do not already address:

- Work with the appropriate institutional leadership to escalate and address any additional threats or risks.

The Role of the HRPP



The Organization

Know the plan.

Periodic evaluation of the plan.

Collaborate with affiliates.

Communicate institutional-level response.



The IRB

Know the plan.

Remain flexible.

Communicate with availability.



Research Personnel

Know the plan.

Consult with the HRPP/IRB.

Follow guidance.

Report safety concerns or problems.

Real Time COVID-19 Response

Incident Command Center established.

Regular communication with Bronson research compliance.

IRB Meetings went virtual holding special meetings for emergency use COVID-19 treatments.

Communication with Center for Clinical Research and other research personnel on the conduct of current research.

Communication with external IRB's.

Provided clarification / guidance with updates and communication from the IRB.

Facilitated with an organization-wide requirement to complete the CITI COVID-19 Return to Campus course.

Real Time COVID-19 Response

Update November 16, 2020:

Due to the increase in patients being treated at our affiliates, processing of submissions that require approval from Bronson Methodist Hospital and/or Ascension Borgess may be delayed. This includes processing of data pull requests.

Working with the IRB Remotely

IRB review of submitted applications will continue as usual. Studies that involve face-to-face interactions cannot begin until after the restrictions are lifted. The IRB is available to assist by calling 269-337-4345. Our remote office hours are M-F 7 am – 6 pm. If you have questions outside of the office hours, email us at irb@med.wmich.edu.

Visit <https://imedris.med.wmich.edu> to access the electronic IRB application.

Face-to-Face Human Subjects Research Activities Restricted Effective March 24, 2020

A Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Human Research Protection Program (HRPP) Guidance Document

This guidance is directed at researchers conducting studies under the oversight of the Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Institutional Review Board (IRB). Given the rapidly evolving circumstances regarding COVID-19 and WMed's focus on the health and safety of faculty, staff, students, and the community, WMed Human Research Protection Program (HRPP) has issued revised standards related to research projects with human subjects and approved by the WMed IRB.

Executive Order 2020-21 (COVID-19) Temporary requirement to suspend activities that are not necessary to sustain or protect life.

Updates

Effective immediately and until further notice, WMed IRB approved **research interactions with human research participants must be performed remotely** (e.g., phone or other online tools such as Zoom, Teams, etc.), unless the research procedure(s) is essential to ensure participant health, safety, or wellbeing. Remote methods of data collection may be conducted if part of the originally approved protocol or an approved modification.

Projects requiring institutional approval may be delayed. All new and existing research activity requiring ancillary services from Bronson and/or Borgess (i.e. data pulls; pharmacy services, etc.) are on hold until further notice.

Please note that the need for face-to-face research visits is extremely unlikely given WMed's research portfolio; however, **research procedures involving face-to-face interaction with research participants must be postponed**, unless the research procedure(s) is essential to ensure participant health, safety, or well-being.

Exception for Essential Research Visits: Research visit(s) that are *essential* to ensure participant health, safety, or well-being may continue using face-to-face interactions if no remote options are available. The decision about whether a research visit is essential to the health, safety, or well-being of a participant is determined by the principal investigator, the participant, and/or the participant's care provider. Decisions must be informed by current public health guidance regarding the COVID-19 outbreak. Decisions about visits should be especially conservative for participants at heightened risk. Research visits for Food and Drug Administration (FDA) regulated clinical trials approved by an external IRB conducted by, or with, WMed's Center for Clinical Research may be exempt from this guidance. Please contact Tom Blok at thomas.blok@med.wmich.edu or Nabil Ghazal at nabil.ghazal@med.wmich.edu for clarification.

Effect of the Restriction on Pending IRB Applications

IRB review of submitted applications will continue as usual. Studies that involve face-to-face interaction may be approved with the condition that face-to-face interactions cannot begin until after the restrictions are lifted.

Notifying Participants of Visit Cancellations

If a study visit needs to be cancelled, participants should be informed of the reason and that they will be contacted again when the visit can be rescheduled. These messages to participants do not require prior WMed IRB approval.

Notifying the WMed IRB

Visit cancellations related to COVID-19 do not need to be reported to the IRB. If you need to adjust data collection procedures during this time (such as conducting phone interviews instead of in person interviews), that adjustment can be made without prior IRB approval. We ask that you report these adjustments in interaction at the time of your next IRB submission.

Contact the Office of the IRB if you have questions at irb@med.wmich.edu or by phone 269-337-4345.