
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.

[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)

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.