Joint Guidance from UMCCTS & UMMS IRB
COVID-19 Guidance for Investigators
Version 1: March 16, 2020

UMMS is implementing aggressive measures to mitigate the spread of COVID-19. This document provides guidance to investigators regarding the conduct of human subjects research during this period.

Relevant Links
https://umassmed.edu/coronavirus
https://www.umassmemorialhealthcare.org/umass-memorial-health-care/patients-visitors/coronavirus-covid-19-news-and-information
https://www.umassmed.edu/ccts/irb/

Q1. Can investigators conduct in-person research visits?

After March 19, 2020, UMMS is restricting human subjects-related research visits to those that are essential to a subject's safety or wellbeing.

This restriction applies to all human subjects research – biomedical, socio-behavioral, or other.

This restriction applies to all non-essential in-person visits – regardless of whether a research visit is scheduled to coincide with a clinical visit or not.

This restriction applies to all non-essential in-person visits – regardless of whether the Clinical Research Center (CRC) is involved.

Q2. Who decides whether in-person research visits are essential?

Whether or not a research visit is "essential to a subject's safety or well-being" is determined by the principal investigator of the research study, the participant, and the participant's care provider, and should be informed by current public health guidance regarding the COVID-19 outbreak. It is the PI's responsibility to lead study staff accordingly.

Please notify the Sponsor of your studies about these changes.

Q3. What about new enrollments?

Enrollment of new patients on a clinical trial will be allowed only if:
1) participation in the trial is critical for the research participant's well-being. These studies must be discussed on a case-by-case basis with the IRB Chair.
Or 2) the trial is focused on evaluation of medications for COVID19 prevention or therapy.

Before enrolling new subjects into studies with in-person visits, the PI should assess

- How might long-term disruptions impair the ability of the subject team to monitor subjects and a subject's ability to participate safely. With respect to ensuring subject safety, the PI should consider the long-term administration of study interventions and investigational products, as well

as the conduct of procedures required to ensure or monitor a subject's safety. *Note that the availability of resources may diminish after a subject enrolls.*
- The potential effect of missed visits on data integrity

Q4. Are there examples of studies that are not essential to a subject's wellbeing or that do not offer a prospect of direct benefit?

Examples of studies not essential to a subject's well-being include (but are not limited to):
- Comparative effectiveness studies
- Biospecimen collection studies
- All non-interventional research

Q5. What about subjects who are already enrolled (i.e., existing enrollments)?

Contact subjects to conduct virtual visits, or to temporarily postpone or cancel in-person research visits that are not essential to the safety or wellbeing of the subject.

Where possible, convert in-person interactions to virtual ones using secure methods – such as REDCap, Qualtrics, Zoom, phone, and secure email.

Do not use Google Docs or Dropbox to communicate with subjects. As a general rule, regular email, text messaging, and voicemail should be handled as though the communications are public. Do not use them for confidential research information.

Q6. What should we do about study specific labs that are required for patient safety?
Labs that are necessary for patient safety must be conducted. As instructed in the 3/12 memo, changes made to protocols in order to eliminate apparent immediate hazards to subjects, including the use of alternate laboratory facilities can be made without prior IRB review and approval. However, they must then be reported to the UMMS IRB within 5 days in accordance with *HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements* (https://www.umassmed.edu/ccts/irb/investigator-guidance/).

Q7. What about subjects who are already enrolled (i.e., existing enrollments) who require study drugs?

The PI will need to work with Investigational Drug Services on any proposed changes in dispensation (IDS@umassmemorial.org). If a PI determines that they can safely dispense and monitor the study drug, and if IDS can support the plan, then this may proceed as a change to eliminate an immediate apparent hazard to subjects.

Study drugs may not be shipped by mail.

Q8. When an in-person visit is essential to a subject's wellbeing, what are the COVID-19 requirements?

The clinical care procedures in effect at the time and location of the visit apply. UMMHC ambulatory clinical/practice procedures include the requirement that all staff and visitors undergo screening for travel, symptoms, and potential exposures.

The study team is responsible to know and adhere to clinical requirements. The requirements outlined below may become more restrictive at any time.

- Accompanying family members are limited to 1 person per study participant
- Twenty-four hours prior to the visit, all research participants should be phone screened for fever, cough and flu-like symptoms by research staff, with repeat screening by research staff at the time of an in-person visit. Those who screen positive will require triage as per UMMHC protocol before being cleared to participate in an in-person research visit. More information on screening and triage is available on the UMMHC coronavirus site https://www.umassmemorialhealthcare.org/umass-memorial-health-care/patients-visitors/coronavirus-covid-19-news-and-information

Q9. What if a visit that is essential to a subject's wellbeing cannot be conducted?

PI's should take steps to minimize potential risks to subjects.

Protocol deviations that increase the risk of harm to subjects must be reported to the UMMS IRB within 5 days in accordance with **HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements** (https://www.umassmed.edu/ccts/irb/investigator-guidance/).

Q10. What if my study is reviewed by an external IRB?

After March 19, 2020, UMMS is restricting human subjects-related research visits to those that are essential to a subject's safety or wellbeing. This includes all research that is reviewed by an external IRB.

Check the external IRB's website for any additional requirements. The external IRB may have different reporting requirements and timelines than the UMMS IRB.

Check the external IRB's applicable SOPs. Contact the UMMS IRB if you are not sure of the applicable SOPs.

Q11. What can investigators do without prior IRB review and approval?

Changes to eliminate apparent immediate hazards to subjects can be made without prior IRB review and approval. However, they must then be reported to the UMMS IRB within 5 days in accordance with **HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements** (https://www.umassmed.edu/ccts/irb/investigator-guidance/).

Q12. What changes require prior IRB review and approval?

All changes require prior IRB review and approval with the exception of changes to eliminate apparent immediate hazards to subjects.

Q13. How should changes be submitted or reported to the UMMS IRB?

Changes to eliminate apparent immediate hazards to subjects must be initially submitted as Reportable New Information. For step-by-step instructions on *How to Submit a Reportable New Information (RNI)*, visit the eIRB Job Aids: https://www.umassmed.edu/ccts/irb/eirb2/job-aids-ii/

An RNI to report a change to eliminate an apparent immediate hazard should describe the hazard, the changes implemented, and any additional information that may inform the IRB's risk assessment.

Changes that are intended to become permanent must (also) be submitted as a Modification.

Q14. What does not need to be submitted or reported to the UMMS IRB?

Study teams do not need to report to the UMMS IRB

- That they have temporarily halted enrollment
- That they have implemented institutionally mandated COVID-19 screening procedures
- Missed visits, study visits out of window, and specific remote visits – so long as these deviations did not put subjects at increased risk of harm

The following should, however, be documented in the study binder

- All temporary changes to enrollment status
- All interactions with research participants, including COVID-19 screening procedures
- All protocol deviations

Notes to file should cite this guidance to document why reporting to the UMMS IRB is not required.

Q15. Do back-up staff need to be CITI trained?

Investigators should consider taking steps to add personnel with the appropriate skills and training as active study staff in eIRB and on delegation logs to ensure coverage.

Investigators may add personnel who have not yet completed online CITI training in human subjects research and, when applicable, good clinical practice (GCP). Relative to the date an individual is added as study staff in eIRB, the UMMS IRB will temporarily permit a 30-day grace period for back-up staff to complete required online CITI training.

Q16. What if the research has external funding?

Investigators should alert their sponsors, program officers, and funders that after March 19, 2020, UMMS is restricting human subjects-related research visits to those that are essential to a subject's safety or wellbeing.

Q17. What if investigators are planning to conduct COVID-19 research?

After March 19, 2020, UMMS is restricting human subjects-related research visits to those that are essential to a subject's safety or wellbeing.

Please contact the UMMS IRB and UMCCTS Office of Clinical Research if you are planning research that is related to COVID-19. Investigators are also advised to contact the Institutional Biosafety Committee.

Q18. How can study staff work on data securely from remote locations?

Visit https://www.umassmed.edu/it/. UMass Med IT has a section devoted to Tools for Working Remotely.

Q19. Are there any tools to document consent in writing remotely?

REDCap supports this feature. Secure email can be used to send scanned documents or pictures of signed consent forms.

Q20. Are the IRB of ORC offices open?

UMMS IRB & OCR Offices are conducting operations remotely until further notice. This will likely result in increased response times, and we thank you in advance for your patience. Our electronic systems, eIRB, OnCore & TRAcs all remain accessible via the web.

Q21. Who should be contacted for questions?

For IRB-related questions: allison.blodgett@umassmed.edu or irb@umassmed.edu
For Office of Clinical Research-related questions: danielle.howard@umassmed.edu or clinicalresearch@umassmed.edu

Prior UMCCTS Memos	
03/12/2020	Changes in Clinical Research Operations due to COVID19
03/12/2020	UMass Memorial Health Care 2019 Novel Coronavirus (COVID-19) Ambulatory Clinic/Practice Procedure AMBULATORY CLINICS v. 03 02 2020
03/12/2020	COVID19-IRB Updates
03/13/2020	COVID 19 Clinical Research Memo March 13