

Joint Guidance from UMCCTS & UMMS IRB COVID-19 Guidance for Investigators Version 6: April 2, 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.

Items updated TODAY are flagged by yellow highlighting: New items in Version 6, April 2, 2020: Revised layout to group by category; updated contacts, notice, and navigational tip; updated duration of measures to May 4th, 2020 (sections [1.0](#), [5.1](#), [5.1.2](#)); clarified studies eligible for new enrollments (section [4.8.1](#)); added section addressing signed consent for COVID-19 related research (section [4.9.2](#)); added table of contents; revised contact question (formerly Q21, now section [3.0](#)) to refer to contacts on page 1; moved relevant links to [appendix A](#); corrected date for Version 4 in [appendix C](#); FDA Guidance Document has been updated (formerly Q23, now section [8.12](#)); added hyperlinked cross-referencing in the document for navigational ease; and other minor formatting, typographical and grammatical corrections

Contacts for Questions:

For IRB-related questions:

Allison Blodgett, PhD, CIP, Director of IRB Operations ----- allison.blodgett@umassmed.edu
Carol Bova, PhD, RN, IRB Committee Chair ----- carol.bova@umassmed.edu
General Contact ----- irb@umassmed.edu

For OCR-related questions:

General Contact ----- clinicalresearch@umassmed.edu
Danielle Howard, Director of Office of Clinical Research ----- danielle.howard@umassmed.edu

For CRC-related questions:

General Contact ----- clinicaltrialsunit@umassmed.edu
Anne Roussell, RN, Director Clinical Research Center ----- anne.roussell@umassmed.edu

NOTICE:

After March 19, 2020, UMMS is restricting human subjects-related research visits to those that are essential to a subject's safety or well-being. (Section [4.1](#))

Any study that is or can be conducted entirely remotely may continue. (Section [4.8.1](#))

TIP:

For faster reference, try pressing "CTRL+F", and entering a keyword relevant to the topic for which you are searching. Otherwise, try holding "CTRL" and left clicking on the desired heading on the table of contents.

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1. How long will these measures last?

We are unsure how long these restrictions will be needed; however, we anticipate that the restrictions will continue until at least May 4, 2020. UMMS understands that these measures are disruptive and may pose financial hardships. Please note that these restrictions will remain in effect until joint guidance is issued from the UMCCTS and UMMS IRB.

2. 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 well-being.

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.

3. Who should be contacted for questions?

Please refer questions to the appropriate party (or parties) as listed in the [Contacts for Questions](#) section on page 1 of this document.

4. Study Subjects / Study Visits

4.1 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 well-being.

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.

This restriction applies to all non-essential in-person procedures – regardless of whether they are timed with an existing clinical visit.

4.2 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 (See [memo](#) in section [8.11](#))

4.3 Can a provider who is also study staff and who sees a subject for a clinical visit conduct non-essential research procedures (e.g., enrollment, survey follow-up, images) at the time of that clinical visit?

No – at this time, clinical visits must be limited to clinical activities (a) to limit person-to-person contact, exposure to equipment, etc., and (b) to maximize the ability of the clinical system to deliver patient care.

4.4 Can study staff retrieve equipment from subjects at the time of the subject's clinical visit?

No – please do not arrange to collect anything from subjects at this time unless it is critical to the subject's wellbeing. The goal is to limit all subject/staff exposure.

Study staff may contact subjects to make arrangements to have them mail equipment back or to ask them to hold equipment until further notice. This would be reported to the IRB as a change to eliminate an apparent immediate hazard to subjects. If there is a specific sponsor that is concerned about equipment, please contact Danielle Howard in the Office of Clinical Research (danielle.howard@umassmed.edu).

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

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. This may include shipping study drug by mail when temperature controls can be met.

The sponsor may elect to ship study drug directly to subjects.

When reporting this to the IRB, please include:

- Confirmation that the study team consulted with both IDS and the sponsor
- A description of any special shipping requirements (e.g., temperature control, signed receipt)

4.6 When an in-person visit is essential to a subject's well-being, 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>

4.7 What if a visit that is essential to a subject's well-being 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/>).

4.8 Enrollment

4.8.1 What about new enrollments?

Enrollment into any study that is or can be conducted entirely remotely may continue. All activities – recruitment, consent, documentation of consent (when applicable), and all other research activities – must be conducted remotely.

Enrollment of new subjects into studies requiring in-person interactions will be allowed only if:

- 1) Participation 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.

Or

- 3) The study involves time sensitive COVID19 research (e.g., biospecimen collection). These studies must be discussed on a case-by-case basis with the IRB Chair.

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

- How long-term disruptions might 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

4.8.1.1 Are there examples of studies that are not essential to a subject’s well-being 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

4.9 How should individuals be consented during this time?

4.9.1 Are there any tools to document consent in writing remotely?

For research that required to be Part 11 compliant under FDA regulations, the UMMS version of [REDCap](#) supports this feature. Alternatively, [secure email](#) can be used to send scanned documents or

pictures/photos of signed consent forms. Research that must be Part 11 compliant should refer to section [4.9.2](#).

4.9.2 How should subjects in COVID-19 therapeutic trials provide signed consent?

If an investigator or study team is approaching individuals to participate in COVID-19 therapeutic trials, there are unique challenges to obtaining written signed consent. Possible exceptions must be conducted in accordance with [HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent – Temporary exceptions for COVID19 therapeutic trials](#).

4.10 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 well-being 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.

5. Clinical Research Center

5.1 Will the CRC be accessible during this time?

Yes – however access will be heavily restricted. As indicated by the recent communication from UMMS leadership, UMMS campus and business unit activities are restricted until May 4th. CRC facilities and staff will continue to support research protocols that are deemed essential to study subjects' well-being. ***At this time, access to the CRC is limited to those individuals that are required to meet the staffing needs of such research protocols. Use of the CRC laboratory for specimen processing is also restricted.***

Any use of the CRC space must be cleared in advance. Please contact Anne Roussel (see Contacts) if access to the space is required.

5.1.1 Will the CRC Laboratory be accessible during this time?

In the event that laboratory access is required for processing, please contact either Anne Roussel or clinicaltrialsunit@umassmed.edu (See [Contacts](#)) to arrange.

5.1.2 How will samples stored in the CRC be accessed?

On Friday, March 20, 2020, all biologic specimens that were stored in the CRC -80 freezer were relocated to Biotech. Relocating the specimens will allow for proper storage and temperature monitoring while CRC access is restricted. Please contact clinicaltrialsunit@umassmed.edu or Anne Roussel (See [Contacts](#)) if you will need access to these specimens prior to May 4th.

6. Data Management

6.1 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*.

7. Specimen Processing

7.1 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/>).

To the extent possible, the use of external labs should be restricted to safety labs. Please be advised that use of external labs has billing implications that have not been resolved.

8. IRB Reporting / Review

8.1 Are the IRB and Office of Clinical Research (OCR) 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.

The IRB is conducting reviews – including reviews of new studies. The Office of Clinical Research is proceeding with all CDA/CTA negotiations. Both offices are giving priority to COVID-19 protocols.

8.2 What can investigators do without prior IRB 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/>).

This means that investigators can move to remote procedures, such as phone or [Zoom](#) interviews, without obtaining prior approval from the IRB.

8.3 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/>

For example, if the protocol is approved to conduct in-person visits and the study team changes them to remote visits to eliminate apparent immediate hazards, this requires reporting to the IRB. This is true even if the change from an in-person visit to a remote visit does not put the subject at increased risk of harm.

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.

A study team may submit one RNI per study to cover all changes to eliminate apparent immediate hazards. As study teams prepare for changes related to the COVID-19 response, they might consider putting together a table for each study that includes:

- a. The visits or procedures
- b. The changes (if any) being implemented to eliminate apparent immediate hazards
- c. An indication of whether each change puts subjects at increased risk of harm,
- d. An explanation as to why or why not
- e. The steps (if applicable) being implemented to minimize risks to subjects, and
- f. A summary of which subjects are affected – without private identifiable information.

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

8.4 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 well-being. 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.

8.5 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.

8.6 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 or study visits out of window – so long as these deviations did not put subjects at increased risk of harm
- A list of specific visits by subjects that have been implemented remotely – so long as the initial report outlined in section [8.3](#) is submitted and so long as there is no new information suggesting that subjects are at an 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.

8.7 Are there any extensions on IRB deadlines?

8.7.1 Expiration Dates

Please review your studies for expiration dates and plan for renewals, as needed. Unfortunately, expiration dates are dictated by the federal regulations and hard coded in eIRB. Therefore, it is not possible for the IRB to issue a grace period on expiration dates. If a study lapses, all human subject research-related activities must stop.

The IRB tries very hard to renew studies before they expire. While we can't promise that we will be able to do so if there is a flood of late submissions, we will give priority to renewals that are essential to the safety or well-being of subjects. Note that these studies typically require review by the convened IRB. Thus, this increases the chance that an essential study may expire before a late continuing review can be reviewed. If a study will expire and the PI believes that subjects may be harmed by stopping human research procedures that are not available outside the human research context, we ask the PI to contact the IRB with a description of the procedures, the potential harm to subjects from stopping, and a brief explanation as to why the procedures are not available outside of the human research context.

8.7.2 Continuing Review Submission Deadlines

Please be reassured that the IRB has never actually placed an investigator on restricted status for missing a deadline for submitting a continuing review. We do not intend to start now. A small amount of wiggle room is built into the existing IRB due dates for submitting a continuing review.

The IRB recognizes that under current circumstances it may not be possible for investigators to meet the continuing review deadlines. We are hopeful that the majority of renewals will be received in time for the IRB to reapprove each study before it expires.

If a continuing review will be submitted late, it may be helpful to hold any modifications until after the continuing review is approved. Plain continuing reviews are typically processed more quickly than continuing reviews that include a modification. Continuing reviews that are complete and that require review by the convened IRB are scheduled for the next available meeting.

8.8 Will the UMMS HRPP be conducting audits during this time frame?

Consistent with social distancing, in-person auditing will not be conducted during this time frame. The UMMS HRPP reserves the right to conduct remote audits where possible.

8.9 How are compassionate or emergency use cases handled?

Please contact IDS, IRB, and OCR.

Relevant worksheets can be downloaded from the IRB website – IMPORTANT – they are not optimized for fast web viewing and must be downloaded and then opened directly:

<https://www.umassmed.edu/ccts/irb/policiesops--checklistsworksheets/sop/>

- [HRP-451 WORKSHEET: Emergency Use Drugs and Biologics](#)
- [HRP-452 WORKSHEET: Emergency Use Devices](#)
- [HRP-453 WORKSHEET: Compassionate Use Devices](#)
- [HRP-454 WORKSHEET: Expanded Access Drugs and Biologics](#)

8.10 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.

8.11 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 well-being. The memo can be downloaded here:

[Memo to share with sponsors re: restrictions on human subjects-related research visits](#)

NIH has issued direct guidance for all NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19. The guidance addresses delays in research progress and unanticipated costs. For details please see:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

8.12 Has the FDA issued any guidance regarding exiting clinical trials?

Yes, the FDA has issued guidance regarding existing clinical trials, including an Appendix addressing Questions & Answers as of Friday, March 27, 2020. For details, please see:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic>

Appendix A: 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/
https://www.umassmed.edu/ccts/covid-19/
https://www.umassmed.edu/research/sponsored-programs/covid-19-resources-for-researchers/
Memo to share with sponsors re: restrictions on human subjects-related research visits
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
https://www.umassmed.edu/globalassets/ccts/other/resources/hrp-803-temporary-covid19-guidance-31mar2020.pdf

Appendix B: 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
03/16/2020	Joint UMCCTS IRB COVID19 Guidance 16mar2020 (Version 1)
03/17/2020	Joint UMCCTS IRB COVID19 Guidance 17mar2020 (Version 2)
03/18/2020	Joint UMCCTS IRB COVID19 Guidance 18mar2020 (Version 3)
03/20/2020	Joint UMCCTS IRB COVID19 Guidance 20mar2020 (Version 4)
03/24/2020	Joint UMCCTS IRB COVID19 Guidance 24mar2020 (Version 5)

Appendix C: Document History

Version 1	March 16, 2020	Initial
Version 2	March 17, 2020	Clarified restrictions on research visits timed with clinical visits, clarified permitted enrollment into studies conducted entirely remotely, added note regarding use of external labs, updated list of prior memos, acknowledged hardship imposed by restrictions, reinserted links, and made minor administrative changes
Version 3	March 18, 2020	Clarified reporting requirements, added information related to audits, added information related to equipment return, confirmed offices open and prioritizing COVID-19 research, added NIH link, flagging updated items with yellow marker
Version 4	March 20, 2020	Added link to FDA guidance for clinical trials, link to OSP page, link to memo to share with sponsors, and information related to continuing reviews and emergency use
Version 5	March 23, 2020	Added notice and tip to top of document. Revision to shipping of study drug to subjects who are already enrolled. Added information regarding sponsor shipments, information related to reporting shipments of study drug to existing enrollments to IRB, information regarding CRC restricted access, and CRC sample access and storage.
Version 6	April 2, 2020	Revised layout to group by category; updated contacts, notice, and navigational tip; updated duration of measures to May 4 th , 2020 (sections 1.0 , 5.1 , 5.1.2); clarified studies eligible for new enrollments (section 4.8.1); added section addressing signed consent for COVID-19 related research (section 4.9.2); added table of contents; revised contact question (formerly Q21, now section 3.0) to refer to contacts on page 1; moved relevant links to appendix A ; corrected date for Version 4 in appendix C ; FDA Guidance Document has been updated (formerly Q23, now section 8.12); added hyperlinked cross-referencing in the document for navigational ease; and other minor formatting, typographical and grammatical corrections