

Joint Guidance from UMCCTS & UMMS IRB COVID-19 Guidance for Investigators Version 9: June 1, 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 9, June 1, 2020: Added section 9 and subsections addressing return to work; Added information re requirements for patients and participants in CRC to section 5.1; Added reminder regarding requirement for MCSR researcher license in section 8.14.1; Updated table of contents; Updated duration of current restrictions to May 31st, 2020, in section 1, 5.1, 5.1.2, 6.2; Updated links in Appendix A; Updated Appendix B and C to reflect revisions for version 9

Contacts for Questions:

For IRB-related questions:

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For OCR-related questions:

General Contact ----- clinicalresearch@umassmed.edu
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For CRC-related questions:

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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 31, 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. **Information regarding the ramping up of research activities can be found in section 9.5.**

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.

Please note, [TRAcS](#) has been updated with options specific to COVID-19 related requests in order to help expedite these requests.

Urgent COVID-19 studies which **DO NOT HAVE** all documents can be submitted as a FastTRAcS submission. FastTRAcS allows for incomplete submission of COVID-19 studies only.

COVID-19 studies with complete materials or non-urgent COVID-19 studies should be submitted in the usual fashion, using the standard options.

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 COVID-19 prevention or therapy.

Or

- 3) The study involves time sensitive COVID-19 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 31st**. 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.

All patients and study participants will require screening for SARS-CoV-2 exposures and symptoms 24 hours prior to visit and again on arrival at the CRC, using a screening script provided by the Office of Clinical Research. Study participants must also follow SARS-CoV-2 infection control policies including the use of masks and social distancing at all times.

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 2. The transfer was carried out at the direction of the Center for Clinical and Translational Science as a part of the aggressive measures to mitigate the spread of COVID-19 and due to the increased restrictions on non-essential personnel in active clinical / research areas. In order to comply with these restrictions, samples previously stored in the CRC laboratory have been temporarily relocated to ensure continuous remote monitoring as well as well as continued access if deemed necessary.

Study teams may reference the CRPG email correspondence on sent on 04/03/2020 or contact the office of clinical research for a copy of the note to file (*UMCCTS – NTF – CRC Sample Transfer – 20200403*) documenting this transfer. This documentation includes:

- How the sample transfer was carried out
- Where samples are now being stored
- What monitoring methods are being utilized
- How samples may be accessed
- Who to contact should study teams have any questions

A copy of the note to file may be provided to your study sponsor if requested, and it should be filed with your significant correspondence in your regulatory binder (if applicable).

Due to the current restrictions in the number of personnel and limited coverage imposed by COVID19, ***please allow 2 to 3 days from time of email request to pick up of samples.*** All requests should include the following information:

- Study Name
- Principal Investigator
- All possible Box Identifiers
- Sample information
- Quantity of requested samples

Please note that all samples are transferred on dry ice. Please bring a closed Styrofoam box or some form of secondary closed container for sample transfer to your lab.

Please contact clinicaltrialsunit@umassmed.edu, Robin Brody (Robin.Brody@umassmed.edu), and Anne Roussell (See [Contacts](#)) if you will need access to these specimens prior to **May 31st**.

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*.

6.2 Are sponsors permitted on campus to monitor studies at this time?

No – *access to the remains heavily restricted* and will remain so until at least **May 31st**. All monitoring activities should take place remotely (see section [6.3](#))

6.3 Can sponsors remotely monitor studies at this time?

Yes – remote monitoring continues to be acceptable and is encouraged for any study teams who require a monitoring visit at this time. Please refer to the [Epic Research Job Aids](#) listed on the OCR webpage and the [EpicCare Link Job Aid – Research Coordinator Workflow](#) (intranet access required).

Requests should be submitted with a reasonable amount of notice prior to the remote monitoring visit.

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.

8.6.1 Are there any tools available to aid study teams in tracking deviations?

Yes – as discussed in the memo, *Tools Available to Study Teams to Aid In Tracking Deviations including Changes to Eliminate Apparent Immediate Hazards*, emailed to the CRPG distribution group, there are two recommended methods for tracking these deviations. The two methods for tracking include:

1. OnCore (Preferred)

Study teams can use OnCore to track deviations and other changes to eliminate immediate apparent hazards. Please see “*OnCore Deviation Work Instruction – Subject Deviations*” within the OnCore Wiki (Intranet - <http://oncorewiki.umassmed.edu/>) for instructions and guidance on how to enter and track deviations in OnCore.

2. Tracking Sheets (Alternative)

Recognizing that not all study teams use OnCore and/or may not be able to use OnCore to track deviations, “Table for Tracking Changes to Eliminate Apparent Immediate Hazards” can be found as an attachment to the CRPG email sent on 04/28/2020 , or can be requested by reaching out to the Office of Clinical Research. This is a tool that study teams can use to organize and track deviations outside of OnCore. For teams with multiple studies, please use a separate tracking sheet for each study.

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. These memos may be shared with sponsors and can be downloaded at the following links:

- [03/13/2020 - Clinical Research Operations and COVID-19](#)
- [04/03/2020 - Updates: Clinical Research Operations and COVID-19](#)

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>

8.13 Do COVID-19 clinical studies have any special research injury compensation language?

Yes, COVID-19 clinical studies should convey the following information in the research injury compensation section:

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427

Sponsors may provide alternative wording.

8.14 Massachusetts Controlled Substances Registration (MCSR) researcher licenses

8.14.1 Do investigators still need to submit applications for MCSR researcher licenses at this time?

Yes – the requirement that investigators obtain a MCSR researcher license (when required) has not changed. A MCSR researcher license is required if:

- If the research involves FDA-approved drugs or is IND exempt: MCSR researcher license can be held by the Department Chair
- If the research involves an Investigational New Drug (IND): MCSR researcher license must be held by the Principal Investigator regardless of who holds the IND.

Investigators are reminded that a failure to obtain their MCSR researcher license may cause significant delays to their study, including their ability to obtain IRB approval.

8.14.2 Do investigators need to renew their MCSR licenses if they are set to expire during the COVID-19 pandemic?

On March 18, 2020, Massachusetts Governor Baker issued an executive order extending the registrations of certain licensed professionals. This order shall remain in effect until it is rescinded or until 90 days after the state of emergency has been terminated, whichever happens first. *However, it is*

expected that PI's will continue to submit their renewal applications in a timely manner to prevent any lapses in licensure and delays in research studies.

A copy of this order can be found here:

<https://www.mass.gov/doc/march-18-2020-extension-of-professional-licensure-order/download>

8.15 How will laboratory accreditations/certifications be impacted?

At this time it is not anticipated that there will be any impact on the Clinical Laboratory Improvement Amendments (CLIA) accreditation, currently not set to expire until 2021.

The College of American Pathologists (CAP) certification is scheduled to expire on May 1, 2020; however CAP has successfully petitioned the Centers for Medicare and Medicaid Services (CMS) to suspend all inspections except Immediate Jeopardy Complaint inspections (and associated follow-up revisit inspections) until further notice. In accordance with this decision from CMS, the CAP has suspended all routine on-site inspections during this national state of emergency due to the COVID-19 pandemic. Once the CAP resumes routine inspections, laboratories will receive prior notification of the inspection date to ensure the inspection can occur as planned. During this time, impacted laboratories will remain CAP accredited.

More information on this change can be found here:

<https://www.cap.org/laboratory-improvement/news-and-updates/cap-inspections-covid-19-update>

9.0 Returning to Work and the Ramping Up of Research Activities

9.1 When will UMMS study staff be able to return to work?

Staff will be returning to campus in phases; however, all Medical School staff must follow [COVID-19 Return to Work Planning](#) when returning to the workplace. See also [Return to Work Resources](#) (<https://www.umassmed.edu/coronavirus/return-to-work-resources/>).

9.2 Will UMMS study staff be required to be tested for COVID-19 prior to returning to work?

Yes – As outlined both [COVID-19 Return to Work Planning](#) and [Return to Work Resources](#), “all study staff under UMMS will be required to complete a coronavirus screening test and be cleared prior to returning to the campus. In addition, all personnel who are to return to campus must begin to self-monitor for symptoms of COVID-19 on a daily basis. This is mandatory. Self-monitoring will be reported via a secure app, and those with symptoms will be asked to call Employee or Student Health Services”. Staff will also adhere to universal use of masks on campus as well as social distancing.

9.3 How should staff conduct self monitoring?

Instructions regarding self monitoring can be found on the [Return to Work Resources](#) (<https://www.umassmed.edu/coronavirus/return-to-work-resources/>) under the header “Self-monitoring app/check in daily”.

9.4 Will any special badge access be required?

At this time, badge access has been heavily restricted. Only staff who have been cleared to return to work will be allowed on the campus.

9.5 When will the campus beginning ramping up research activities?

As described in the memo “Clinical Research Ramp Up” issued on May 14, 2020, research activities will begin to ramp up as follows:

Tentative Effective Date #	Clinical Research Activity Permitted
Current	COVID-19 clinical trials. Follow-up of study subjects enrolled in any human subjects research that is essential to the well-being of the individual; follow-up on any study or clinical trial that can be conducted remotely. New enrollments into non-COVID-19 research that is essential to the wellbeing of a subject continue to require permission of the IRB Chair.
June 1, 2020	ADD: Scheduled follow-up visits for ongoing studies that are required to conduct safety assessments (labs and exams that are important for patient safety due to the administration of study drug or devices)
June 15, 2020	ADD: New enrollment into existing or opening new trials that hold out the potential of benefit to subjects (no longer limited to only those studies that are essential to the well-being of subjects)
TBD	All other studies

Note:

- All Medical School staff must follow [COVID-19 Return to Work Planning](#) when returning to the workplace. See also [Return to Work Resources](#).
- All dates are subject to UMMHC and department-specific restrictions on clinical activities, and may be advanced or delayed depending on circumstances.
- Daily activity that utilizes space in the Clinical Research Center continues to be restricted at this time, as a portion of the CRC is currently being utilized for COVID-19+ patient research (see section [5.1](#)).

9.6 When will site initiation / monitoring visits be allowed to resume?

At this time, site initiation and monitoring visits will still be required to be conducted remotely. Research teams will be notified at a later date once these visits are allowed to resume on site.

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/
Changes in Clinical Research Operations due to COVID-19 (https://www.umassmed.edu/globalassets/ccts/other/resources/ccts-covid19-communication-march-12re.pdf)
Clinical Research Operations and COVID-19 (https://www.umassmed.edu/globalassets/ccts/other/resources/covid-19-clinical-research-memo-march-13.pdfdistribution.pdf)
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
HRP-803 Investigator Guidance - Documentation of Informed Consent- Temporary Exceptions for COVID19 Therapeutic Trials https://www.umassmed.edu/globalassets/ccts/other/resources/hrp-803-temporary-covid19-guidance-31mar2020.pdf
CRC Protected Unit Opening Today (https://www.umassmed.edu/globalassets/ccts/other/resources/umccts---memo---crc-protected-unit.pdf)
Changes in Clinical Research and Operations due to COVID-19 - Updated 4/3/2020 (https://www.umassmed.edu/globalassets/ccts/other/resources/umccts---memo---covid-19-clinical-research---update1---03032020.pdf)
Epic Research Job Aids (https://www.umassmed.edu/ocr/epic-research-job-aids/)
COVID-19 Collaboration Platform (https://covidcp.org/)
March 18, 2020 – Extension of Professional Licensure Order https://www.mass.gov/doc/march-18-2020-extension-of-professional-licensure-order/download
CAP Inspections COVID-19 Update https://www.cap.org/laboratory-improvement/news-and-updates/cap-inspections-covid-19-update
May 14, 2020 - Clinical Research Ramp Up Memo https://www.umassmed.edu/globalassets/ccts/other/clinicalresearchrampupmemo-20200514.pdf
UMMS Return to Work Resources https://www.umassmed.edu/coronavirus/return-to-work-resources/

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)
04/02/2020	Joint UMCCTS IRB COVID19 Guidance 02apr2020 (Version 6)
04/13/2020	Joint UMCCTS IRB COVID19 Guidance 13apr2020 (Version 7)
04/28/2020	Joint UMCCTS IRB COVID19 Guidance 28apr2020 (Version 8)

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
Version 7	April 13, 2020	Added sections 6.2 and 6.3 to clarify monitoring of studies by sponsors during this time; section 8.13 added to address COVID-19 specific injury compensation language; updated section 2 to include TRAcS guidance for COVID-19 related research; updated section 5.1.2 to further clarify access to samples previously stored in the CRC laboratory and the transfer of these samples to Biotech 2; updated Appendix A for additional relevant links as well as fixing broken links, Appendix B and Appendix C updated to reflect updated documents
Version 8	April 28, 2020	Updated duration of these changes through May 18 th ; Updated section 5.1.2 to further clarify how to obtain samples previously stored in CRC laboratory; Added section 8.6.1 "Are there any tools available to aid study teams in tracking deviations?"; 8.14 (and sub-sections) "Massachusetts Controlled Substances Registration (MCSR) researcher licenses"; section 8.15 "How will laboratory accreditations/certifications be impacted?"; Linked to COVID-19 Collaboration Platform, as well as including links referenced in sections 8.14 and 8.15 to Appendix A ; updated version log in Appendix B ; change log updated in Appendix C

Joint Guidance from UMCCTS & UMMS IRB COVID-19 Guidance for Investigators
Version 9: June 1, 2020

Version 9	June 1, 2020	Added section 9 and subsections addressing return to work; Added information re requirements for patients and participants in CRC to section 5.1 ; Added reminder regarding requirement for MCSR researcher license in section 8.14.1 ; Updated table of contents; Updated duration of current restrictions to May 31 st , 2020, in section 1 , 5.1 , 5.1.2 , 6.2 ; Updated links in Appendix A ; Updated Appendix B and C to reflect revisions for version 9
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