

**Joint Guidance from UMCCTS & UMMS IRB
COVID-19 Guidance for Investigators
Addendum Version 9: March 24, 2021**

UMMS has implemented 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. In an effort to more quickly communicate changes with study teams, this addendum will only address current issues/topics.

Items updated TODAY are flagged by yellow highlighting: New items in Addendum Version 9, March 24, 2021: Added Health and Safety Precautions at beginning of document; Updated [Section 1.4](#) (and subsections) to reflect changes to state and institutional to travel guidance; [Section 2.1](#) to reflect changes for teams utilizing CRC space; [Section 4.2](#) (and subsections) to reflect changes to on site monitoring policy; [Appendix B](#), [Appendix C](#). Minor typographical and grammatical revisions.

Contacts for Questions:

For IRB-related questions:

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Carol Bova, PhD, RN, IRB Committee Chair ----- carol.bova@umassmed.edu
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For OCR-related questions:

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

For CRC-related questions:

General Contact ----- clinicaltrialsunit@umassmed.edu
Bethany Trainor, RN, Clinical Research Nurse Manager ----- bethany.trainor@umassmed.edu

NOTICE:

Restrictions pertaining to human subjects-related research were lifted, effective June 23, 2020, with the exceptions noted in this document.

In-person interactions with participants in human subject's research studies currently remain open.

Study teams are reminded to watch for updates as they become available. Updates related to research will continue to be posted to <https://www.umassmed.edu/ccts/covid-19/>

All UMMS COVID-19 guidance, forms and resources continue to be available at <https://umassmed.edu/coronavirus/>.

Health and safety precautions

Everyone – vaccinated or not – must continue to follow all COVID-19 safety protocols.

- If COVID-19 symptoms develop at any time, stay home, call Employee Health Services at (508) 793-6400 or Student Health Services at (508) 334-2818.

- Stay physically distant when possible.
- Wash your hands frequently.
- Always wear a mask, indoors and outdoors, while on campus, even in elevators, parking garages and when waiting for the garage shuttles. The only time you may remove your mask is when you are alone in your office. Please dispose of masks responsibly.
- Continue weekly COVID-19 surveillance testing if you are on campus two or more days a week.

We thank all UMMS clinical research investigators and staff for working with us to ensure that we can continue to provide critical research resources, while ensuring that we do not burden our clinical partners during the provision of routine clinical care.

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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1.0 Resumption of Research Activities

1.1 Adherence to Massachusetts state guidelines

Study teams are required to follow the Massachusetts state guidelines related to COVID-19. This includes [travel restrictions](#) for members of the study team, study participants, and anyone accompanying a study participant.

1.2 Adherence to institutional restrictions

Study teams are required to adhere to any clinical restrictions imposed by UMMHC or other applicable health care facilities being utilized. Departments will differ. Principal Investigators should help study teams navigate the research activity conduct in a manner that is respectful of clinical needs. These restrictions include any travel restrictions and policies put into place by the institutions, in addition to the state requirements.

1.3 Research Visits

Study teams should continue to conduct any visits for enrolled subjects remotely when possible, as allowed by the sponsor. As stated in [Job Aid for Reopening Human Subjects Research – V1.0 – June 19, 2020](#), “Investigators are permitted to use remote procedures for enrolled subjects, such as phone or Zoom interviews, without obtaining prior approval from the IRB. These changes, however, must be submitted promptly as Reportable New Information, and they must be incorporated into the Investigator Study Plan at the next regularly scheduled Modification or Continuing Review.”

Study teams are reminded that patients and study participants are expected to comply with all travel restrictions and policies (as described in sections [1.4](#))

1.4 Travel Restrictions and Policies / Visitor and Vendor Policies

Please note, travel policies apply to both sponsored and personal travel.

Prior to any travel

Before **any** out-of-state travel, employees and students must complete a UMMS/UMMHC travel form and are advised to review the current [federal](#) and [Massachusetts](#) guidance, which can change at any time.

- UMMS employees working on campus in medical school buildings, clinical research sites, DMH facilities or working remotely should use [this travel reporting form](#).
- UMMS employees working in UMass Memorial clinical care settings should complete the [UMass Memorial form](#) and email it to [Employee Health COVID-19 mailbox@umassmemorial.org](mailto:Employee_Health_COVID-19_mailbox@umassmemorial.org).
- Students should complete the [student travel form](#).

1.4.1 UMMS Travel Policy

Study teams should continue to regularly review the [UMMS travel guidance page](#) for the most up-to-date information regarding UMMS travel policies. This travel policy applies to all UMMS employees and nonclinical students at all sites, including individuals returning to work, and new hires.

1.4.2 Massachusetts Travel Advisory

As of Monday, March 22, Governor Baker's Travel Order has now been updated to a travel advisory. A copy of Governor Baker's Travel Advisory can be found Here: <https://www.mass.gov/info-details/covid-19-travel-advisory>. All visitors entering Massachusetts, including returning residents, are advised to quarantine for 10 days upon their arrival. Travelers in the following categories are exempt from this quarantine advisory:

- Travelers who have received a negative COVID-19 result on a test administered not more than 72 hours prior to their arrival in Massachusetts. Travelers may also test out of the quarantine advisory after arrival in Massachusetts, as long as they quarantine until receiving a negative test result.
- Anyone who is entering Massachusetts for fewer than 24 hours
- Anyone who is returning to Massachusetts after being out of the State for fewer than 24 hours
- Workers who enter Massachusetts to perform critical infrastructure functions (as [specified by](#) the Federal Cybersecurity and Infrastructure Security Agency) during required commuting to or from work and while at work.
- Travelers who are fully vaccinated (i.e. who have received two doses of either the Moderna or Pfizer COVID-19 vaccines OR who have received a single dose of the Johnson & Johnson vaccine, 14 days or more ago) and who do not have symptoms.

All travelers are encouraged to consult and follow the [CDC's guidelines and requirements for travel](#).

1.4.3 Visitor and Vendor Policy

1.4.3.1 UMMS Visitor and Vendor Policy

UMMS is updating their visitor and vendor policy regularly. A copy of the current policy can be found here - <https://www.umassmed.edu/parking/visitor-management/>. For information related to site initiation, monitoring, and close out visits, please see section [4.2](#).

1.4.3.2 UMMHC Visitor Policy

UMMHC is updating their visitor policy regularly. Please refer to the appropriate campus for the most current visitor policy.

- [UMass Memorial Medical Center](#)
- [UMass Memorial Health Alliance – Clinton Hospital](#)
- [UMass Memorial – Marlborough Hospital](#)

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

Yes – So long as study staff continue to act within UMMHC/UMMS guidelines, retrieval of equipment is being permitted during normally scheduled visits, so long as it can be done safely. During this time study staff should ensure that all equipment is decontaminated according to institutional and study guidelines.

However, if equipment cannot be retrieved in the course of a normal visit, it should be delayed. 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).

1.6 Will influenza shots be required for staff this fall?

Yes – [As communicated on September 14, 2020](#), all UMMS employees who plan to enter any of the medical school buildings for even one day from Oct. 1, 2020 through April 1, 2021, and all UMMS students, are required to receive a flu vaccine by Dec. 15, 2020.

Please note:

- UMMS will offer influenza vaccinations free of charge to all employees and students.
- Flu shots will be given by appointment only; no drop-ins are allowed.
- Individuals who receive a flu vaccine through services other than Employee or Student Health Services (e.g. physician's office or pharmacy) must provide proof of immunization to EHS/SHS by Dec. 15, 2020.
- Remote employees who will not be accessing the campus during the window listed above are not required to receive the influenza vaccination, however it is still strongly encouraged.

Further instructions and information can be found with the official communication – [here](#).

1.7 Proper use of PPE

Effective November 10, 2020, UMMHC has approved a new [policy for personal protective equipment \(PPE\) requirements](#) for all caregivers.

What are the main components of the new policy?

- The use of surgical masks is required in all clinical and non-clinical settings, unless you are alone in an enclosed office.
- Only surgical masks provided by UMass Memorial will be allowed for use. Homemade masks cannot be used either alone or in combination with another mask.
- Eye protection is required for clinical care areas and is strongly recommended in all non-clinical care areas.
- Caregivers who wear eyeglasses will be required to use additional eye protection, as eyeglasses do not provide adequate side protection.
- Procedure or condition-specific guidance for PPE should still be followed as appropriate, i.e., C.diff., MRSA, central line placement, etc.

What do I need to know about eye protection?

- Acceptable eye protection for clinical areas:
 - For COVID-19 positive patients or patients under investigation (PUI) – Face shield or goggles
 - For COVID-19 negative patients or surveillance test-pending patients, as well as those deemed at low risk for COVID-19 based on symptoms – Face shield, goggles, two-piece eye protection or safety glasses
- Acceptable eye protection for non-clinical areas include face shield, goggles, two-piece eye protection, or safety glasses
- Providers should obtain the appropriate eye protection from any inpatient floor or any clinic.
- All eye protection is meant to be reused and should NOT be used as a single use item. It should be replaced only if the eye protection becomes damaged or is soiled and unable to be adequately wiped down.

What is the definition of clinical care area?

Clinical care area is defined as an area used for patient care and treatment or is regularly accessed by patients when visiting a UMass Memorial site for any purpose. Clinical care areas also include, but are not limited to, patient rooms, inpatient units, ambulatory clinics and waiting areas, clinical laboratories, elevators, lobbies, food service areas/cafeterias and other areas regularly accessed by patients when visiting any UMass Memorial site.

Please note, proper eye protection will now be required to be used in the CRC.

Studies teams should obtain PPE through their departments and ensure adherence to UMMHC and other institutional requirements. If they have questions about ordering, please contact Eric Stratton (eric.stratton@umassmed.edu).

2.0 Clinical Research Center

2.1 Will the CRC be accessible during this time?

Yes – the CRC is accessible, and the facilities and staff continue to support research protocols. Access is limited to those individuals that are required to meet the staffing needs of research protocols. For questions about the use of the CRC laboratory, see section [2.2](#).

All staff who are accessing the CRC one or more days a week must undergo weekly screening for COVID per UMMS policy and must adhere to proper use of PPE, including proper eye protection.

Use of the CRC space **must** be reserved in advance using the UMMS Room Scheduler as the primary method to request all space. This will allow research staff to view available space and request specific CRC rooms and resources. All requests should be submitted at least 2 business days in advance and will be reviewed by the CRC team. Please contact Bethany Trainor (see [Contacts](#)) with any CRC related questions.

Clinic and Study teams are reminded that they are required to prescreen all patients and study participants who will be seen in the CRC and must utilize the CRC phone screening script (Current Version – Version 2 / 07/31/2020). Study teams may request a copy of this script by emailing Bethany Trainor (see [Contacts](#)) or Eric Stratton (Eric.Stratton@umassmed.edu). In the event of any COVID-19 signs/symptoms/or exposures, it is recommended that visits be postponed whenever possible, or otherwise must be scheduled for use of the negative pressure room in the CRC.

All study participants MUST adhere to both state and institutional travel policies.

Effective immediately, clinic patients, for clinical care, and research subjects may be seen in the CRC. All groups must continue to adhere to institutional policies and the [Mass COVID-19 Travel Advisory](#).

In addition, adults and children whose visit includes PFT's will require a COVID-19 PCR test within 72 hours prior to their visit regardless of whether the visit is clinical or research.

Study teams are reminded to discuss and report these changes with sponsors and the IRB as required. Additionally, the Office of Clinical Research will have no control over billing conducted at outside laboratories. Collection of lab certifications, reference ranges, will also likely be required by study teams, along with possibly adding labs to the 1572 where applicable.

Please contact Bethany Trainor (see [Contacts](#)) with questions related to the CRC.

2.2 Will the CRC Laboratory be accessible during this time?

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

Samples from patients and participants who are either confirmed or suspected of being COVID+ cannot be processed in the CRC laboratory; study teams should arrange sample collection and processing by the Biorepository by contacting Karl Simin at Karl.Simin@umassmed.edu at least 2 business days in advance.

3.0 IRB Reporting / Review

3.1 Standard Guidance

With the resumption of research activities on the campus effective June 23, 2020, standard guidance for research activities should be followed unless otherwise stated. Questions, concerns, or requests for clarifications should be sent to the appropriate individual listed in the [Contacts](#) section.

3.2 CITI Training

Previously, relative to the date an individual was added as study staff in eIRB, the UMMS IRB had been permitting a 30-day grace period for back-up staff to complete required online CITI training. However, with the lifting of restrictions on June 23, 2020, all study staff are expected to have appropriate training before being added as study staff in eIRB.

3.3 Has UMMS HRPP resumed conducting audits?

Yes - HRPP has resumed conducting audits. The CCTS Quality Improvement Manager will be communicating directly with study teams to schedule and conduct any audits that had been postponed due to COVID-19. If you need to request an audit of a study, or you have questions about the audit process, please contact Eric Stratton (eric.stratton@umassmed.edu).

In order to adhere with social distancing guidelines and remote work schedules, debriefings following the QA audit may be scheduled via zoom. In-person access to research records is still required during the QA audit.

Due to the numerous and rapid changes to policies due to COVID-19, it is recommended that study teams consider conducting a self-inspection or review of their study records (site file, subject records, etc.) to ensure compliance with all applicable regulations and policies. A copy of the QI/QA Inspection Checklist and Investigator Self-Assessment (and instructions) can be found [here](#).

4.0 Data Management / Services

4.1 Can DocuSign be used for research records, logs, notes-to-file?

At this time, the UMMS version of DocuSign is not considered to be part 11 compliant, and therefore may not be used for research records, logs, or notes-to-file that require compliance with FDA 21 CFR Part 11.

We are currently working on setting up a part 11 compliant DocuSign system, and further guidance will be released when this becomes available. Please note that there will be additional charges to sponsors and study teams for use of the part 11 DocuSign system.

4.2 Monitoring

4.2.1 When will site initiation / study monitoring / close-out be allowed to resume in-person visits?

Remote monitoring remains the preferred and recommended method for site visits, however study teams housed in UMMS space will now be permitted to have on-site visits by individuals from study sponsors and/or CRO's, with restrictions. These individuals and study teams will be required to adhere to institutional and state policies. Documentation of vaccination status, negative PCR test, and/or other

items required in conjunction with the SV3 visitor management system must be collected and retained by the study teams, and be immediately available in the event of a QA audit.

In some instances, both UMMS and UMMHC policies may apply. For example, study teams housed in UMMS space, but requiring access to IDS for monitoring visits, must adhere to both UMMS and UMMHC policies (as IDS is housed in UMMHC space).

At this time only one monitor will be allowed for visits.

Questions or concerns regarding site initiation / monitoring / close-out may be sent to Eric Stratton, Quality Improvement Manager, CCTS (Eric.Stratton@umassmed.edu).

4.2.2 What tools are available to assist in remote monitoring?

The following resources are available to teams utilizing remote monitoring:

- Epic
 - [Epic Research Job Aids](#) listed on the OCR webpage
 - [EpicCare Link Job Aid – Research Coordinator Workflow](#) – Updated Aug 13, 2020 (intranet access required)

EpicCare Requests should be submitted with a reasonable amount of notice prior to the remote monitoring visit. Remote monitoring of Epic records should only be conducted through EpicCare Link, and not through Zoom or WebEx.

Please note that only documents directly related to treatment should be uploaded into Epic, as this is the patient's legal medical record. Items such as patient diaries, questionnaires, and logs, for example, should not be uploaded into Epic.

- Zoom
 - The Medical School uses the HIPAA compliant version of Zoom exclusively. Zoom may be used to share screens for remote monitoring and review of documents not available in Epic. If using Zoom, study teams should ensure that both a passcode and waiting room are used to ensure that unauthorized persons are not able to join the meeting. Zoom is available for free to all UMass Medical School or Commonwealth Medicine employees with a @umassmed.edu email. Accounts can be requested [here](#) (UMMS Intranet).
- WebEx
 - For UMMHC personnel, HIPAA compliant WebEx is available for use for review of documents not available in Epic. Please note that there is a cost to the department per account. Study teams may request an account [here](#) (UMMHC Intranet).

NOTE: For study teams that are working to review regulatory or subject binders via HIPAA compliant Zoom or WebEx, an external webcam can be set up to be aimed downward at the binder as a document reader to help facilitate faster, remote review of documents.

- MoveIT

- MoveIT is a secure file transfer software provided through UMMS IT that may be utilized if approved in a study's monitoring plan. PHI should not be shared unless it has been specifically approved by the IRB in the study ISP and consent. Additional information about MoveIT can be found here: <https://www.umassmed.edu/it/security/secure-data-transfer-guidance/>

4.2.3 What should I do if monitors require access/information from IDS?

In person access to IDS is now allowed, however, study teams must obtain approval from UMMHC prior to the visit and adhere to the guidance of UMMHC policies as well as section 4.2.1. In person monitoring visits will be limited to one person and must be scheduled with IDS in advance.

Any continuing remote monitoring visits with IDS must be scheduled in advance – ideally two or more weeks in advance. All requests should include the following:

- Date IDS documents will be needed
- Where/to whom documents are to be sent
- List of all documents from IDS which the CRA is requesting
- IDS cannot always honor requests for temperature logs from the present month; please let the CRAs know that the sponsor, PI and study team would be made aware of any excursions
- Effective October 30, 2020, the IDS policy around returns will be strictly enforced. IDS will be destroying all returned drugs on site at the University and Memorial campuses.
- IDS is not able to accommodate screen sharing or video visits; please make the CRAs aware of this limitation.

Direct all inquiries for monitor visits, subject visits, etc. to: <mailto:ids@umassmemorial.org>

4.3 Where has the FastTRAcS option gone?

TRAcS should continue to be used for all studies. Due to decreased urgency for implementing COVID-19 studies at UMMS, the COVID-19 FastTRAcS option in TRAcS has been disabled. TRAcS will continue to ask you to identify COVID-19 related study requests in order to prioritize requests, but requests for services for COVID-19 studies will be entered using the usual menu options.

If you have a COVID-19 study that requires an urgent response and you don't have the required documents to complete the request, please enter as much information as you can into TRAcS and contact the UMCCTS Clinical Research Navigator, Ann Han (ann.han@umassmed.edu).

4.4 Interpreter Services for Research Activities

Study teams should be aware that the visitor restrictions at UMass extend to interpreter services (both clinical and research). This may affect a study team's ability to conduct the short form informed consent process. Over the phone and video interpreter services for research are available, however the LanguageLine interpreter services for research studies is unable to provide a witness signature on the short form, which is required for FDA-regulated research ([45 CFR §46.117\(b\)\(2\)](#) & [21 CFR §50.27\(b\)\(2\)](#)) as well as research conducted under the purview of UMMS ([HRP-802](#)).

There is a local interpreter service provider who has a HIPAA compliant zoom platform and is willing to provide remote video services and coordinate for a witness signature via fax or picture, however, study teams will need to provide as much lead time as possible before the informed consent meeting. Study teams will also need to be able to fax or e-mail a copy of the informed consent and short form for the interpreter.

Please be aware that some languages will be easier to provide on short turnaround than others. Study teams should plan accordingly.

In addition, it would also be possible to use a subject's family member observing remotely via video, but study team's will need to figure out the logistics of collecting their signature on the short form.

4.5 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 had previously been postponed due to COVID-19. It has since been conducted, and the current laboratory certifications can be found here on the UMMHC Clinical and Anatomic Pathology page [here](#) (UMMHC Hub).

More information on this change can be found here:

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

Appendix A: Relevant Links

Massachusetts COVID-19 Travel Advisory https://www.mass.gov/info-details/covid-19-travel-advisory
UMMS - Corona Virus Updates https://umassmed.edu/coronavirus
UMMHC – Turning the Tide on COVID-19 https://www.umassmemorialhealthcare.org/turning-the-tide-covid-19
UMMS IRB https://www.umassmed.edu/ccts/irb/
UMMS CCTS - Coronavirus (COVID-19) Related Guidance to Researchers https://www.umassmed.edu/ccts/covid-19/
UMMS OSP - COVID-19 Resources for Researchers https://www.umassmed.edu/research/sponsored-programs/covid-19-resources-for-researchers/
Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html
FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
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
UMMS Return to Work Resources https://www.umassmed.edu/coronavirus/return-to-work-resources/
New mandatory flu immunization policy at UMMS https://www.umassmed.edu/news/news-archives/2020/09/new-mandatory-flu-immunization-policy-at-umms/
EpicCare Link – Research Coordinator Workflow https://teams.umassmemorial.org/sites/jobajds/JobAids/Shared%20Documents/Epic%20Carelink%20for%20Study%20Monitor.pdf
UMMHC - New policy for personal protective equipment (PPE) requirements for all caregivers https://www.umassmemorialhub.org/documents/personal-protective-equipment-requirements-covid-19

Appendix B: Prior UMCCTS Memos

Note: Items below are hyperlinked with the exception of items marked with an asterisk (*).

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)
03/31/2020	HRP-803 Investigator Guidance - Documentation of Informed Consent- Temporary Exceptions for COVID19 Therapeutic Trials
04/02/2020	Joint UMCCTS IRB COVID19 Guidance 02apr2020 (Version 6)
04/03/2020	CRC Protected Unit Opening Today
04/03/2020	Changes in Clinical Research and Operations due to COVID 19 [Update 1]
04/13/2020	Joint UMCCTS IRB COVID19 Guidance 13apr2020 (Version 7)
04/28/2020	Joint UMCCTS IRB COVID19 Guidance 28apr2020 (Version 8)
04/29/2020	Changes in Clinical Research and Operations due to COVID 19 [Update 2]
05/14/2020	Clinical Research Ramp Up Memo
06/01/2020	Joint UMCCTS IRB COVID19 Guidance 01jun2020 (Version 9)
06/15/2020	Clinical Research Phase II June 2020
06/19/2020	Job Aid for Reopening Human Subjects Research – V1.0 – June 19, 2020
07/20/2020	Joint UMCCTS IRB COVID19 Guidance 20jul2020 (Addendum Version 1)
08/06/2020	Joint UMCCTS IRB COVID19 Guidance 06aug2020 (Addendum Version 2)
08/13/2020	Joint UMCCTS IRB COVID19 Guidance 13aug2020 (Addendum Version 3)
10/05/2020	Joint UMCCTS IRB COVID19 Guidance 05oct2020 (Addendum Version 4)
11/12/2020	Joint UMCCTS IRB COVID19 Guidance 12nov2020 (Addendum Version 5)
11/18/2020	Joint UMCCTS IRB COVID19 Guidance 18nov2020 (Addendum Version 6)
11/25/2020	Joint UMCCTS IRB COVID19 Guidance 25nov2020 (Addendum Version 7)

Appendix C: Document History

Version 1	July 20, 2020	Initial
Version 2	August 06, 2020	Added highlighting; section 1.4 and subsections addressing travel restrictions and policies; Added section 4.2.2 addressing tools are available to assist in remote monitoring; Added section 4.4 addressing interpreter services for research activities; Added appendices A, B, and C; Updated section 2.1, 2.2, 4.5, appendices A (updated links), B (directly linked to documents), and C.
Version 3	August 12, 2020	Updated section 1.4 and subsections addressing travel restrictions and policies; Updated section 4.2.2 addressing tools are available to assist in remote monitoring; Updated appendices A , B , and C
Version 4	October 5, 2020	Added section 1.6 re influenza policy; section 4.2.3 re monitoring of IDS; Updated section 1.4.1 re UMMS Travel Policy; section 3.3 re QA audits, section 4.2.2 re remote monitoring tools; Appendix A , Appendix B , Appendix C .
Version 5	November 12, 2020	Added Section 1.4.3 Visitor and Vendor Policy; Section 1.7 Proper use of PPE per new UMMHC requirements; Updated section 2.1 to reflect need for screening of staff working in CRC one or more days a week; Appendix A , Appendix B , Appendix C . Minor typographical and grammatical revisions.
Version 6	November 18, 2020	Updated Notice to reflect recommendation for planning for possible restrictions; section 1.7 and section 2.1 for clarification re new PPE requirements; Appendix A , Appendix B , Appendix C . Minor typographical and grammatical revisions.
Version 7	November 25, 2020	Updated Section 2.1 to reflect new restrictions to patient and research subjects utilizing CRC space. Appendix B , Appendix C . Minor typographical and grammatical revisions.
Version 8	March 24, 2021	Added Health and Safety Precautions at beginning of document; Updated Section 1.4 (and subsections) to reflect changes to state and institutional to travel guidance; Section 2.1 to reflect changes for teams utilizing CRC space; Section 4.2 (and subsections) to reflect changes to on site monitoring policy; Appendix B , Appendix C . Minor typographical and grammatical revisions.