

**Joint Guidance from UMCCTS & UMMS IRB
COVID-19 Guidance for Investigators
Addendum Version 2: August 6, 2020**

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 2, August 6, 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](#).

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 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.

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 as they resume research activities. Principal Investigators should help study teams navigate the resumption of research 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

1.4.1 UMMS Travel Policy

Effective July 24, 2020, UMMS has updated their travel policy due to a rising number of Coronavirus cases around the United States. All UMMS students and employees are required to adhere to this policy. All travel outside of New England, New York, and New Jersey requires reporting using the this [form](#).

A copy of this policy can be found here: <https://www.umassmed.edu/news/news-archives/2020/07/updated-travel-policy-related-to-covid-19-in-the-us-and-abroad-july-24/>.

Further information and travel guidance from UMMS can be found here: <https://www.umassmed.edu/coronavirus/travel-guidance/>.

In contrast to [Governor Baker’s policy](#), UMMS does **not** accept a negative COVID-19 PCR test within 72 hours of return as an exemption to the quarantine.

1.4.2 Massachusetts Travel Order

Governor Baker has also issued an updated to his COVID-19 Travel Order, effective beginning August 1, 2020. A copy of Governor Baker’s Travel Order can be found Here: <https://www.mass.gov/info-details/covid-19-travel-order>.

Pursuant to that order, “All visitors entering Massachusetts, including returning residents, who do not meet an exemption, are required to:

- Complete the [Massachusetts Travel Form](#) prior to arrival, unless you are visiting from a lower-risk state designated by the [Department of Public Health](#).
- Quarantine for 14 days or produce a negative COVID-19 test result that has been administered up to 72-hours prior to your arrival in Massachusetts.

If your COVID-19 test result has not been received prior to arrival, visitors, and residents must quarantine until they receive a negative test result.”

Further information regarding the Massachusetts Travel Order, as well as a list of exemptions, can be found at the link above.

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).

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.

Use of the CRC space should 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.

Study teams 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). **All study participants MUST adhere to both state and institutional travel policies.**

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.

All samples that had previously been transported from the CRC to the Biotech 2 laboratory have been returned. This transfer occurred over two days (7/31/2020 & 8/3/2020) to minimize temperature fluctuations in the CRC -80 freezer. A note to file has been distributed to the CRPG mailing list for use as study documentation. Study teams may may contact Bethany Trainor (see [Contacts](#)) to request a copy of the note to file, or with any questions regarding the transfer.

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 your study need to request an audit please contact Eric Stratton (eric.stratton@umassmed.edu).

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 part 11 compliance.

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?

While some access to the campus by outside essential personnel has been eased at this time, *restrictions for visits by sponsor/CRO personnel will remain restricted until further notice*. At this time, all monitoring activities should continue to take place remotely. The Office of Clinical Research will communicate to study teams once these types of visits are being permitted to take place in-person.

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](#) (intranet access required)

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

Please note that only documents directly related to treatment should be uploaded in to 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 (Preferred Method)**
 - 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. 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. Teams are strongly encouraged to use Zoom.
- **WebEx**
 - If a study sponsor can provide an attestation as to HIPAA compliance for WebEx, this is acceptable to use in place of Zoom for remote monitoring and review of documents. A copy of this attestation should be documented in the regulatory binder prior to use of WebEx.

As a reminder, UMass Medical School employees with an official affiliation with UMass Memorial Health Center are reminded to always use the UMass Medical School HIPAA compliant Zoom account with their name@umassmed.edu email address and the UMass Memorial Telehealth ZOOM account with their name@umassmemorial.org email address.

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

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/

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)

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.