# Joint Guidance from UMCCTS & UMMS IRB COVID-19 Guidance for Investigators

## Addendum Version 1: July 20, 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.

### 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.

## 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 *Governor Baker's COVID-19 Travel Advisory – July 1, 2020*, and that "All travelers to Massachusetts, including Massachusetts residents returning home, from states other than Rhode Island, Connecticut, Vermont, New Hampshire, Maine, New York, and New Jersey, are required to self-quarantine for 14 days." In addition, all patients and study participants will require screening for SARS-CoV-2 exposures and symptoms 24 hours prior to visit and again on arrival. Study participants must also follow SARS-CoV-2 infection control policies including the use of masks and social distancing at all times.

### 1.4 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 (as described in section 1.3) and must utilize the CRC phone screening script.

### 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.

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 please contact Eric Stratton (eric.stratton@umassmed.edu).

# 4.0 Data Management

## 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.

## 4.2 When will site initiation / study monitoring be allowed to resume in-person visits?

While some access to the campus by outside essential personnel is being eased at this time, restrictions for visits by sponsor/CRO personnel 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.

The following resources are available to teams utilizing remote monitoring:

- Epic Research Job Aids listed on the OCR webpage
- 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.

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

## 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).