



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

TO: University of Massachusetts Medical School Faculty and Staff

FROM: Katherine Luzuriaga, MD, Vice Provost for Clinical and Translational Research
Danielle Howard, Director, Clinical Research Operations

DATE: March 12, 2020

RE: Changes in Clinical Research Operations due to COVID19

As indicated by the recent communication from UMMS leadership, UMMS campuses and business units remain open and healthy staff should come to work. UMCCTS leadership is taking the following steps to assist with efforts to slow the community spread of the virus, while ensuring that clinical research, which often provides access to critical therapeutic options, can continue.

General:

- Investigators and study staff who are ill should not come to work.
- Investigators and research staff should work with sponsors and collaborators to conduct study-related business virtually as much as possible.
 - This may include modification of protocols to allow virtual visits. Additional information from the UMMS IRB regarding the appropriate process for making changes to clinical studies in response to the current COVID-19 epidemic will be issued shortly. The process will make use of federal regulations that permit study teams to implement changes to eliminate an immediate apparent hazard and to then notify the IRB within 5 days.
 - We are encouraging virtual site initiation and closeout visits, wherever possible.
 - In person site initiation visits and study visits should be discussed with managers. Visitors should be kept to a minimum.
- Accompanying family members should be limited to 1 person per study participant.
- Investigators and study staff can access lists of scheduled study visits (and visit windows) by running the Subject Visit Detail report in OnCore, which should facilitate planning.

Clinical Research Center Operations & Screening: Effective March 12th, the CRC will adopt all UMMHC ambulatory clinical/practice procedures (see attached), including the requirement that all staff and visitors to the unit will undergo screening for travel, symptoms, and potential exposures.

- Study teams should contact study participants 24 hours prior to each visit to conduct screening of study participant and accompanying family member. Study visits should be re-scheduled for those that indicate travel or exposure to individuals with possible COVID19. Any subjects that indicate symptoms compatible with COVID19 will be referred to their clinical health provider; the study team should work with the provider to provide appropriate study follow-up.
- Screening will be repeated by CRC staff on arrival at the CRC. If a patient/ study subject presents with symptoms compatible with COVID19, a CRC nurse will contact the appropriate health care provider and infection control per UMMHC procedure.
- To facilitate screening:
 - DMD, ALS, and Dermatology clinic staff and patients should use the current waiting room.
 - All research staff, including those requiring access to the lab or other CRC facilities, and study subjects should use the old waiting room. Staff screening should be completed once daily.

Study Coverage: Study teams should actively plan for coverage of research-related business in the event that staff and colleagues may be out of work due to travel-related quarantine, illness or the need to care for a loved one who is ill. For IRB approved studies, coverage must take into account the skills

and training needed to conduct research procedures. Appropriate personnel should be added in eIRB and added to delegation logs in anticipation of changes.

UMCCTS staff are here to assist you/your study team with questions during this time. Additional updates will be provided as UMMS and/or UMMHC policies change, and as the situation warrants.

As indicated by earlier UMMS communications, the purpose of these measures is to do our part to slow the spread of the virus and does not imply a significant health risk. The UMCCTS will continue to work with UMMS leadership to assure the health and safety of our community.

Blodgett, Allison

From: Blodgett, Allison
Sent: Thursday, March 12, 2020 7:20 AM
To: IRB
Subject: COVID19-related IRB Updates

Dear Research Community,

The UMMS IRB Office remains open, and our electronic submission system, eIRB, remains accessible via the web. Our Ask-An-Expert sessions will not be held this month.

Because of COVID-19, researchers may need to implement changes to research studies in order to eliminate apparent immediate hazards to subjects. For example, study teams may need to conduct scheduled visits by phone instead of in-person, arrange for blood draws at commercial labs in order to minimize potential exposure to COVID-19, or add research personnel who are not yet CITI certified in order to ensure staffing levels and provide for back-up coverage. **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/>).** If your study is reviewed by an external IRB, please check the applicable SOPs as timelines and reporting processes may be different.

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/> If you are submitting an RNI to report a change to eliminate an apparent immediate hazard, please describe the hazard, the changes implemented, and any additional information that may inform the IRB's risk assessment.

Study teams should actively plan for coverage of research-related business in the event that staff and colleagues may be out of work due to travel-related quarantine, illness, or the need to care for a loved one who is ill. For IRB approved studies, coverage must take into account the skills and training needed to conduct research procedures. Appropriate personnel should be added in eIRB and added to delegation logs in anticipation of changes.

Study teams do not need to report to the UMMS IRB that they have implemented institutionally mandated COVID-19 screening procedures prior to in-person visits. However, all interactions with research participants should be documented in the study binder.

The IRB will continue to work with UMMS leadership to assure the health and safety of our community.

Sincerely,
Allison

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The University of Massachusetts Medical School's [Human Research Protection Program](#) has been awarded full accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

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