



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: June 15, 2020

RE: **Phase 2: Clinical Research Ramp Up (June 23-August 1)**

In follow-up to the May 14th memo, we are writing to inform faculty of the revised plan for ramping up clinical research affected by the COVID-19 Pandemic. Phase 2 of the UMMS re-opening will begin on June 23rd and last through at least August 1st. In keeping with this and to ensure that we do not burden our clinical partners as they re-open for routine clinical care, the clinical research ramp up will move forward on June 23rd (formerly June 15th). Additional guidance will be provided as more information becomes available.

Tentative	
Effective Date #	Clinical Research Activity Permitted
Current	<p>COVID-19 clinical trials. Follow-up of study subjects enrolled in any human subject’s 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.</p> <p>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).</p>
June 23, 2020	<p>ADD: New enrollment & all other research visits into existing or new trials. Clinical research and clinical trials visits will no longer be limited to those that are essential to subjects’ well-being or to studies that offer a prospect of direct benefit to subjects.</p> <p>Rare exceptions may be granted for individual study visits prior to June 23rd on a case-by-case basis. Any request must be submitted to Dr. Carol Bova, IRB Chair (Carol.Bova@umassmed.edu) with a justification for the exception, confirmation that study staff who meet the criteria to return to work are available to staff the visit, and confirmation that the clinical setting is able to accommodate the research.</p>

Please Note:

- ALL UMMS employees must be tested before returning to campus. Study teams are responsible for coordinating testing through their departments. Additional information about testing UMMS employees is expected to be released this week.

- All UMMS employees must follow [COVID-19 Return to Work Planning](#) when returning to the workplace. See also <https://www.umassmed.edu/coronavirus/return-to-work-resources/>.
- Study teams/departments are responsible for obtaining their own PPE.
- 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 is restricted through at least July 1st, as part of the CRC is currently being utilized for COVID-19+ patient research. Please contact Bethany Trainor, RN (Bethany.Trainor@umassmed.edu) for availability.
- CRC study visits will require screening for COVID exposures and symptoms 24 hours prior to visit and again on arrival at the CRC. Study participants and research staff must use follow COVID-19 infection control policies including social distancing at all times and the use of masks.

Study teams are reminded to review the document Joint Guidance from UMCCTS & UMMS COVID-19 Guidance for Investigators (<https://www.umassmed.edu/ccts/covid-19/>) for additional updates.

Please contact Danielle Howard (Danielle.Howard@umassmed.edu) with any questions or concerns.