

- 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: May 14, 2020

RE: Clinical Research Ramp Up

As a follow-up to the communication issued on April 29, 2020, we are writing to remind faculty and staff that after March 19, human subjects-related research visits are restricted to those essential to a subject's well-being. The reduction in activities has been extended and will remain in place through at least May 31, 2020.

Please see below for the current plan for ramping up clinical research affected by the COVID-19 Pandemic. We will continue to provide further guidance as more information becomes available and as we near June 1.

Tentative Effective Date #	Clinical Research Activity Permitted
Current	COVID-19 clinical trials. Follow-up of study subjects enrolled in any human subjects 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.
June 1, 2020	ADD : 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)
June 15, 2020	ADD : New enrollment into existing or opening new trials that hold out the potential of benefit to subjects (no longer limited to only those studies that are essential to the well-being of subjects)
TBD	All other studies

Notes:

- All Medical School staff must follow <u>COVID-19 Return to Work Planning</u> when returning to the workplace. See also <u>https://www.umassmed.edu/coronavirus/return-to-work-resources/.</u>
- 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 continues to be restricted at this time, as a portion of the CRC is currently being utilized for COVID-19+ patient research.

 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 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 (<u>https://www.umassmed.edu/ccts/covid-19/</u>) for additional updates.

Please contact Danielle Howard (<u>Danielle.Howard@umassmed.edu</u>) with any questions or concerns.