

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

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RE: Joint Guidance Document Retirement

In alignment with the UMMS guidance for returning to campus, and the improving trend of COVID-19 cases, the CCTS is revising our guidance to study teams and retiring the document *Joint Guidance Document: Addendum Version 9*, dated March 24, 2021. However research teams are reminded of the following:

- Study teams and subjects must continue to adhere to institutional infection control, travel, visitor, and vendor policies. *Study teams should refer directly to the appropriate institution (UMMS, UMMMC, Community Healthlink, etc) for these policies*. This includes use of visitor/vendor management systems when required by the institution (e.g., <u>SV3</u> for UMMS).
 - o <u>UMMS Travel Guidance</u>
- Remote monitoring is still recommended when possible.
 - Vendors and visitors who are not fully vaccinated and are entering Massachusetts for fewer than 24 hours are expected to obtain a negative COVID-19 PCR obtained within 72 hours of arrival into Massachusetts and be able to present it to their host if requested.
- All UMMS COVID-19 guidance, forms and resources continue to be available at https://umassmed.edu/coronavirus/
- UMMMC guidance and visitation information can be found at the following links:
 - o <u>https://www.ummhealth.org/covid-19-latest-information-and-resources</u>
 - o https://www.umassmemorialhub.org/coronavirus-information-for-employees (Internal)
 - <u>https://www.umassmemorialhub.org/departments/information-our-caregivers-</u> <u>systemwide</u> (Internal)
- 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>
- Study teams must continue to adhere to institutional policies regarding PPE, social distancing, and masking, as required.
- The document <u>HRP-803 Investigator Guidance: Documentation of Informed Consent –</u> <u>Temporary exceptions for research requiring written documentation of consent during the</u> COVID-19 pandemic remains in effect until further notice.
- CRC study visits continue to 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.

Please feel free to contact Eric Stratton (eric.stratton@umassmed.edu) with any questions or concerns.