

TO: All Faculty, Staff, and Students

FROM: Dennis S. Charney, MD
Anne and Joel Ehrenkranz Dean
Icahn School of Medicine at Mount Sinai

Rosalind J. Wright, MD MPH
Dean for Translational Biomedical Sciences
Icahn School of Medicine at Mount Sinai

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RE: COVID -19 Clinical Research Guidance Update #3

As has been stressed in previous clinical research guidance reports, it is paramount that we protect the health of patients and our workforce and preserve resources to address the pandemic, and, as such, Mount Sinai is standing down much of our human subjects research and modifying other existing protocols. At the same time, we want to protect the integrity of our research protocols, for which our patients have selflessly volunteered to participate in. In addition, as the pandemic continues to evolve, we will increasingly be prioritizing COVID-related research efforts across our health system.

We felt it would be helpful to summarize where we are and to offer further specific guidance as this dynamic situation continues to evolve:

- We are **suspending in-person screening and enrollment visits** in our clinical research studies, with the exception of studies evaluating interventions for COVID-19 or for other life-saving interventions. Please contact your IRB to ensure that your study falls in this category as previously advised.
- We are **suspending in-person follow-up visits** for all subjects unless discontinuing or deferring the protocol presents a clear and present harm to the study patient (see previous guidance).
- For patients already enrolled or randomized, please continue to collect **protocol-specified data remotely via telephone or telehealth if possible**. Data elements that can be collected remotely include medication adherence, quality of life and functional status instruments, hospitalizations, adverse events and complications. You can contact Yvette Hutson, Yvette.Hutson@mountsinai.org, in the Institute for Transformative Clinical Trials for consultation on methods for remote follow-up.
- **Extension** of protocol-defined **data collection windows**, where possible, will provide flexibility and will minimize data loss. Obviously, late data is better than no data.
- Remote data collection and extension of data collection windows are strategies that can be implemented as modifications for previously approved research, as stated in 45 CFR 46.108 and 21 CFR 56.108 (to eliminate immediate hazards to human research subjects). Below, we provide some language that investigators may want to use to notify the IRB.

We anticipate that data collection on the (...) trial will occur via telephone, or, when the data collected are required to be collected in-person, out of the protocol-defined study visit window. The study sponsor is aware of this change in practice and encourages us to capture data in a manner that would best protect our participants' health. We will record the details of each out of window visit and provide a summary to you at the time of our next continuing review request. The original protocol-defined study visit windows will be reinstated once our local guidelines allow for the resumption of on-site clinical research assessments.