TO: All Faculty, Staff, and Students

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

Eric Nestler, MD, PhD
Dean for Academic and Scientific Affairs
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

Given the evolving nature the COVID-19 outbreak we wanted to reach out to the research community with guidance regarding clinical research at the MSHS.

First, we want clinical research to continue to the maximal extent possible during this evolving crisis.

In the abundance of caution, effective immediately, we urge research teams to increase use of remote monitoring/follow up (i.e., telephone, Zoom, Skype, etc) in order to reduce non-essential in-person study visits at the health system when possible. While we urge researchers to consider appropriate modifications to their protocols to limit face-to-face visits, we want to ensure that our research program continues. Research studies having circumstances where this cannot be fully implemented will be assessed on a case-by-case basis to develop an acceptable contingency strategy. If your research protocol includes aerosolizing procedures (e.g., spirometry, nasal/oral swabs or brushings, induced sputum, etc.), you should seek further guidance by emailing rosalind.wright@mssm.edu.

In situations where face-to-face contact may be necessary, research staff should follow institutional guidelines related to COVID-19. In order to ensure the safety of our patients and our staff we strongly urge everyone to call study participants ahead of their visits to screen for potential respiratory symptoms and travel. You can find the MSHS
COVID-19 Screening Algorithm, as well as other useful information, here: http://intranet1.mountsinai.org/inf_ctrl2/Corona_Virus/Corona_Virus_Landing.html. The infectious diseases screening tool, http://intranet1.mountsinai.org/inf_ctrl2/NEW%20WEBSITE/Infectious%20Diseases%20Screening%20Tool%205Feb18.pdf, is administered at all points of entry (i.e., ED, clinics, and urgent cares). All study teams should implement this for research study visits. If a patient has recently travelled to an affected area (see CDC list of affected countries, https://www.cdc.gov/coronavirus/2019-ncov/summary.html) and has symptoms of an upper or lower respiratory tract infection, COVID-19 should be considered. The study participant and any accompanying persons should be offered surgical masks and immediately be moved to an airborne isolation room (if available) or a single room with the door closed. Research staff should contact the covering investigator/clinician immediately if not present for the study visit. Clinicians are asked to practice standard, contact, and airborne precautions with the addition of eye protection (face shield or goggles). Individuals donning a N95 respiratory should be fit tested. Please take a history including the travel history, potential exposure history, and symptom history. Please call Infection Prevention at your site if you do encounter a study participant where COVID-19 is in the differential.

Importantly, if any staff is ill with respiratory symptoms: DO NOT come to work and follow sick leave policy. In addition please use meticulous hygiene. The virus can survive on surfaces for a few hours up to several days so staff should disinfect all surfaces before and after each study participant visit (e.g., exam tables, desktop tables, etc.).

Thank you and please feel free to reach out with questions. We will continue to update you as the situation evolves.