

TO: All Faculty, Staff, and Students

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RE: **COVID -19 Clinical Research Guidance Update #2**

As the COVID-19 pandemic continues to evolve, the impact on New York Metropolitan area will only intensify. In addition to free movement being sharply curtailed, the area's health systems brace for equipment, supply, room and personnel shortages. It is imperative that the Mount Sinai Health System and the Icahn School of Medicine at Mount Sinai preserve its resources and maintain the health of its workforce. We also have an ethical and legal obligation towards those subjects enrolled in research studies; we must minimize the subjects' risks. This reality is driving the need to stand down many of our current human subject research projects at ISMMS and modify many of the others.

We want to be clear that continuing visits should occur only if discontinuing or deferring the protocol presents a clear and present harm to the study patient. **If you plan to continue any such visits, you must discuss this with the PPHS ASAP, before visits can continue.** Failure to defer or modify a protocol consistent with this policy will be considered non-compliance by the PPHS, and may be a reportable event to outside agencies, funders etc.

Once you have been approved to continue by PPHS you will be instructed to notify the IRB office via email that you will be submitting a protocol amendment in context of the COVID pandemic in the next 72 hours and then submit a modification within the next 2 weeks.