TO: All Faculty, Staff, and Students

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RE: Ramping up on-site not for benefit clinical research

The New York metropolitan region has made great strides in managing the COVID pandemic, to the point where the city should begin reopening from June 8th. Starting May 18th, we initiated Phase 1 for restarting essential face-to-face research visits for projects that have a possibility of direct benefit to participants. We commend the research community for your adherence to the guidelines set forth for that first step to ensure a successful reopening thus far. Building upon that and with the upcoming New York State and New York City relaxation in restrictions, in Phase II which will begin June 8th, we will also begin allowing the resumption of face-to-face research that does not hold out the prospect of direct benefit to participants.

It is the intention of the ISMMS to expand clinical research activities in a safe manner that does not needlessly endanger subjects, staff, or clinical care at the hospitals and clinics. There is a fundamental principle in research oversight that requires research to be conducted in a manner that minimizes risks to subjects, consistent with sound research design. Importantly, this is not a return to pre-COVID normality and our success will again depend upon our research community adhering to the following guidance.

To that end:

- All subjects coming on campus or a Sinai office site must to follow current COVID protections concerning pre-visit screening, temperature checks, wearing masks, etc.
    - It is the responsibility of the research team to reach out to participants within 24 hours of scheduled face to face visit(s) to conduct pre-visit screening for COVID-related symptoms and reiterating visitor policy.
    - All hospital, departmental and clinic rules regarding COVID-19 prevention must be adhered to once research subjects arrive on campus, including but not limited to pre-visit screening at an established ambulatory practice area, the Health System's Visitor Policy, lab testing, etc.
- All subjects should be made aware of the risks involved with traveling to the medical center and being seen face-to-face.
- Efforts should be made to minimize the face-to-face exposure, both the duration and number of episodes. This means that activities that can be done remotely should be done remotely. This may

include all or part of the informed consent process, completion of questionnaires, and rating scales etc. Activities that are tied to clinical visits should also be adopted to minimize time and disruption to clinic operations.

- Subjects that are at increased risk of COVID morbidities, e.g. age, obesity, diabetes, heart disease, etc. should be identified and the research procedures should be modified or postponed to minimize risks.
- Scheduling has to be tightly coordinated to location and should reflect added time to clean rooms, get through screening, etc.
- All research visits must be scheduled in such as a way as to minimize waiting and crowding in order to maintain social distancing and minimize the impact on clinical activities if that applies. These should be coordinated at the local level.
- All recruitment activities taking place in clinic waiting areas or clinic office space are considered suspended. Activities may be allowed only with approval of the PPHS and will require appropriate assurances that the activities are consistent with current hospital rules and have the permission of the clinic.
- Procedures that generate aerosols are not approved at this time (e.g., spirometry, sputum induction).

Implementation:

- All projects need to obtain departmental approval before resuming face-to-face visits with subjects.
- All projects planning to reinitiate face to face encounters must complete a short online form found here: PPHS Not-for-Benefit Research Ramp up Form
- As the form will make clear, if you can attest to departmental approval, that the basic steps outlined in the above guidance have been taken to minimize risks, and that higher risk subjects are not involved in the research, then increased on-site activities may begin upon completion of the form.
- As the form will make clear, for other projects where special precautions have to be considered to protect subjects at increased risk for complicated and fatal COVID outcomes, more formal patient notification will be required and a specific mitigation strategy has to be reviewed by the PPHS. You **MAY NOT** begin on-site activities until receiving notification from the PPHS. The PPHS will endeavor to review these within 2 working days of submission.

If you have any further questions, comments or suggestions please contact the IRB at IRB@mssm.edu or Lori.Jennex@mssm.edu. You can also reach out to Rosalind Wright, MD MPH at rosalind.wright@msssm.edu.