

## Cancer Clinical Trials Office (CCTO) Contingency Response to COVID-19

March 16, 2020

In accordance with the COVID -19 Clinical Research Guidance issued by the ISMMS and to maintain the safety of our patients, research staff and faculty, we would like to provide additional recommendations regarding clinical research policies from the Tisch Cancer Institute. As emphasized in the COVID-19 Clinical Research Guidance Update from March 16, 2020:

*Only essential face to face visits should occur, where the benefits to subjects outweigh these expanded risks. Researchers should not recruit subjects to come to clinical research sites solely for the purpose of clinical research follow-up visits as this constitutes unnecessary exposure issues. This includes subjects involved in ongoing multi-visit protocols - unless postponing follow-up constitutes a safety issue to the subject, every attempt should be made to re-schedule these visits. If the PI determines that a subject needs to be seen you must follow the institutional guidelines for screening for coronavirus, which have been previously circulated and can be found here on the MSHS intranet, prior to seeing these participants.*

To address this effort, the following plans should be put into place to protect our study patients/participants:

1. We are encouraging every research team to review all upcoming study visits and to decide which visit is an essential visit and therefore requires an in-person visit and which can be converted to MSHS telehealth/phone, delayed to a later date, or omitted. We would like disease team physician leaders to work closely with the research staff to review these lists in detail and provide feedback to the RTC leadership on updated clinic numbers.
2. Essential on-site study visits are those deemed by the patient's care provider, the study PI, and the participant as those essential for a participant's health or well-being. We leave this to each treating provider to determine. Examples include visits for treatment, critical safety checks, and lab work needed for treatment decisions. Visits to maintain adherence to a protocol that do not directly impact on the patient's health or wellbeing (i.e. PE visits, investigational blood draws or biopsies) are not considered essential and the patient should NOT be seen in person for these visits.
3. Please move as many non-essential visits to the MSHS telehealth platform or phone as possible. This includes safety checks that do not require an in-person visit. If you decide that a patient visit can be moved to MSHS telehealth or phone call, please try to notify the patient prior to asking your Practice Coordinator to re-schedule. Research nurses will email or call to advise patients about any scheduling change and assist with telehealth access if necessary. Once this preliminary contact is done, the Practice Coordinator can be notified to contact and move the patient's appointment.



**Telemedicine instructions/requirements:**

1. Patient has mychart app, smart phone, and adequate internet access
  2. NYS resident
  3. Request to create telemed visit and activate
  4. Log into the visit within 60 min of appointment time
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4. According to the **attached NCI memorandum**, The Responsible Investigator for a patient already enrolled on a clinical trial may make appropriate arrangements with a Local Healthcare Provider to provide certain study activities in order to provide continuity of care and follow-up study visits when the patient cannot travel to the site location of the Responsible Investigator. In this situation, the Local Healthcare Provider is providing intermittent/short-term care and the Responsible Investigator believes it is in the patient's best interest to continue study activities. The activities provided by the Local Healthcare Provider must be conducted under the oversight of the Responsible Investigator in accordance with the protocol and with assurances that processes are in place to report all required information to the Responsible Investigator who is responsible for ensuring that the data is entered into the data management system for the trial.
  5. Oral investigational medication pickup visits that do not need an in person visit, may be able to be changed if the research team can coordinate with the investigational pharmacy to FedEx some medications to participants. This will be on a case-by-case basis.
  6. Research blood draws can be performed, processing of the blood can be performed at the discretion of the individual principal investigator and research team.
  7. Enrollment of new patients onto an interventional clinical trial is allowed, but only if participation in the trial is essential to the participant's health and/or wellbeing. If the treatment or intervention can be delayed, it should be. Research staff will continue to be able to review eligibility check lists and provide faculty with enrollment materials (ICFs, etc.). In an effort to keep non-essential staff outside of clinic areas, CCTO strongly suggests utilizing e-signatures when possible (i.e. regulatory documents, disclosures, etc.).
  8. Enrollment of new patients to non-therapeutic trials where enrollment and participant management of patients can be conducted remotely for the duration of the COVID19 outbreak is permitted.
  9. All essential visits must be preceded by a remote (phone) screen by the RTC nursing staff with repeat screening by clinical staff at the time of arrival.

In regard to the ISMMS COVID-19 Clinical Research Guidance Update which states:

*To the extent possible, researchers and research staff should work from home and identify remote means of continuing productivity and subject follow-up via Zoom meetings, phone interviews, electronic survey tools, etc.*



We have the following plan for our CRC and regulatory personnel:

1. Effective today, all CRC's are being given the option of working from home on a rotating schedule to allow coverage for all disease teams.
2. Please remember that CRC's are not health professionals, and have not received training with regards to infection control, etc.
3. If a patient is having biospecimens acquired that are essential to the patient's health and well-being (e.g. a SOC biopsy), they should be handled in standard fashion using clinical personnel. If a patient is having a SOC biopsy and that includes concurrent collection of a research specimen, the CRC will still retrieve and send off the research specimen.
4. The Program for the Protection of Human Subjects (PPHS) is aware deviations will occur (i.e. missed labs). Research teams have been instructed to keep track of all deviations and submit them weekly or monthly depending on volume. For external IRBs (i.e. BRANY, CIRB), please follow their reporting policies (**see attached PPHS research alert communication**).
5. It is expected that all projects will be conducted in compliance with the latest Health System and School guidelines around COVID-19 prevention, detection and treatment as it affects subjects and research personnel, including screening before arrival, use of PPE, etc. Without waiting for PPHS approval, protocol changes to achieve this should be implemented immediately, and/or protocols should be paused until those requirements can be met (**see attached research alert communication**).

If you have any regulatory questions, please contact your regulatory compliance coordinator or Tiffany Drummond, Assistant Director of Regulatory Affairs ([tiffany.drummond@mssm.edu](mailto:tiffany.drummond@mssm.edu)).

6. Study integrity is important, however, it should not lead to policy violation or putting individuals, whether they be patients, care-givers, or research support staff at increased or unnecessary risk.
7. Effective immediately, all on-site sponsor visits, whether for site initiation, site qualification or monitoring are postponed. Decisions about remote monitoring, or requests for an in-person monitoring visit for patient safety will be addressed by Lisa Gaynes, Executive Director- CCTO ([lisa.gaynes@mssm.edu](mailto:lisa.gaynes@mssm.edu)).

We will continue to respond to any additional changes in policies from Mount Sinai Hospital and ISMMS. Please feel free to contact Dr. Karyn Goodman ([Karyn.goodman@mountsinai.org](mailto:Karyn.goodman@mountsinai.org)), Dr. Matthew Galsky ([Matthew.Galsky@mssm.edu](mailto:Matthew.Galsky@mssm.edu)) or Lisa Gaynes ([lisa.gaynes@mssm.edu](mailto:lisa.gaynes@mssm.edu)) if you have any questions or concerns.