MSK CR Activities relating to COVID-19	Explanation of Protocol Plans
Written Consent obtained over the Phone	Conducting the consent discussion on the phone with a faxed/emailed consent for signature is allowable without IRB approval and should be properly documented in the patient health record. Obtaining only verbal consent when a paper document is not available is not permitted unless allowed in your protocol or approved on an individual basis by the IRB Chair/HRPP Director for urgent cases in which patient's life is in jeopardy.
Protocol Deviations	MSK IRB/PB enacted changes to the 'Deviation To IRB Approved Research and IRB SOPs', RR-407, effective immediately. See attached. IRB prospective deviation approval is **not required** for the following: • Pharmacy shipping drug to another Center or participant home • Dispensing additional self-administered drug • Eligibility: for emergent cases, if allowable by the sponsor. A Retrospective Deviation must be submitted after enrollment and proper documentation written into the chart outlining which eligibility criteria wasn't met and why treatment was needed urgently for participant. A note to file must be sent to the IRB (not in real time) and placed in the regulatory binder. The note to file must include impacted participants and reason for change in practice and policy. IRB retrospective deviation reporting for delayed tests/visits/treatments, missed tests/visits/treatments must be managed in the following way: • Documentation in the EMR outlining what was missed and reason • A note to file must be sent to the IRB and placed in the regulatory binder (not in real time). The note to file must include impacted participants and reason for change in practice and policy. The research community will be alerted with any additional updates to above changes and when regular reporting resumes.
Continued supply of Oral Investigational Product	MSK will utilize all possible means to ship Investigational Product to Patient and/or Local Pharmacy. MSK will (as needed) provide multiple cycles of Investigational Product if there is the potential patient will not be able to return to MSK facility. Patients will be reminded to complete Pill Diaries daily.

	If patient is unable to come to an MSK facility their care on Investigational Product will be monitored for safety, and appropriately documented. A request for additional drug supply will be made, as needed.
Continued treatment of Protocol Patients	As travel restrictions increase and/or if a patient is unable to travel to site, MSK CR Staff will inform the appropriate Study Monitor/CRA. We hope to work with Study Monitor/CRA on the best options to continue treatment. An appropriate document will be made available in the patient health record and CRFs.
Laboratory and Imaging Assessments	If we are unable to perform the collection at an MSK Facility due to restrictions, advise to perform blood and urine dipstick tests at local laboratory as feasible, please ensure the local laboratory results are entered in the CRF. There may be a direct impact to our ability to draw and ship research labs, as per protocol. Appropriate notification and documentation will be made. If unable to attend the visit due to restrictions, please investigate if an assessment can be arranged at a local facility.
Monitoring Visits	Data entry, query resolution and submission of scans will proceed as expected. Onsite monitoring visits have been suspended until further notice. Remote monitoring (Emonitoring) will continue as scheduled. Study Teams will contact Monitor/CRA by phone/email to make arrangements to review the data entry, query resolution, scans shipment, subjects impacted in order to keep you updated regarding Protocol status. MSK is working on getting as many monitors in remote monitoring as possible.