



DATE: June 8, 2020

TO: CUIMC IRB Principal Investigators and Study Coordinators

FROM: Brenda Ruotolo, Executive Director, Human Research Protection Office/IRBs

RE: Human Subjects research activities

Currently at CUIMC essential research both in the laboratory and with human subjects is ongoing, and this will remain the case until NYC enters Phase 2 of the Governor's restart plan.

When Phase 2 begins in NYC, and the University approves Phase 2 activities, human subjects research will restart in priority-based tiers that reflect discussions of the Research Restart Committee. Priorities 1 and 2 will re-open as of the University's start date, and later priorities at 2 week intervals subsequently, with ongoing re-assessment of issues that may arise during the restarting process. The IRB will reactivate the protocols without specific requests to do so from investigators. Investigators will receive e-mail notifications of re-activation from the IRB that can be provided to sponsors, DSMBs, and others as needed. Such emails will be sent for each study, whether it is conducted at CUIMC, in NYC, or elsewhere. A decision to restart in-person activities at locations outside of NYC must take into account the status of the pandemic in that area.

Please see [Frequently Asked Questions](#) for additional information.

Priority I:

The following human subjects research that are currently paused or modified to completely remote procedures, are permitted to recommence during the ramp-up of Priority I research:

- Existing clinical trials that offer the prospect of direct benefit.
- In-person, on-site clinical research in which the research activity occurs during inpatient stays or during an already scheduled clinical outpatient visit.
- Enrollment of new subjects must remain on hold unless one of the following criteria are met:
 - COVID-19 clinical research and trials
 - Enrollment of clinical trials that offer the prospect of direct benefit.
 - Enrollment is conducted remotely, and study procedures do not require in-person contact.
 - On-site clinical research in which the research activity occurs during inpatient stays or in the Emergency Department
 - Exception granted by the IRB.

Priority II:

The following human subjects research that are currently paused or modified to completely remote procedures, are permitted to recommence during the ramp-up of Priority II research:

- Existing clinical research that offers the prospect of direct benefit.
- Existing and new clinical trials and research, funded by federal or foundation sponsors and does not meet the criteria in Priority I.
- Enrollment of new subjects must remain on hold unless one of the following criteria are met:
 - COVID-19 clinical research and trials
 - Enrollment of clinical trials that offer the prospect of direct benefit.
 - Enrollment is conducted remotely, and study procedures do not require in-person contact
 - Enrollment of new subjects in clinical trials and research, funded by federal or foundation sponsors.
 - Exception granted by the IRB.

Priority III:

The following human subjects research that are paused or modified to completely remote procedures, are permitted to recommence during the ramp-up of Priority III of research:

- Existing clinical trials and research, funded by an industry sponsor and does not meet the criteria in Priority I and II.
- New clinical research and trials that meet the criteria in Priority I and II.
- Enrollment of new subjects can be initiated for those studies which are not paused.

Priority IV:

The following human subjects research that are paused or modified to completely remote procedures, are permitted to recommence during the ramp-up of phase IV of research:

- All human subjects research (new and existing) not included in Priority I – III. Examples include:
 - Observational studies without potential for direct benefit
 - Pharmacokinetic studies
- Research previously conducted remotely may return to on-site if desired.
- No restrictions on enrollment of study subjects.

Questions should be directed to irboffice@columbia.edu. Thank you as always for your commitment to the ethical conduct of human subjects research.