Date: March 11, 2020

To: IRB protocol principal investigators

From: Brenda Ruotolo, Executive Director, Columbia University Human Research Protection Office/IRBs

Re: Research involving in-person participant contact & the evolving COVID-19 outbreak

Given the current COVID-19 coronavirus outbreak, and the real or perceived risk of exposure, the risk/benefit ratio for research participation must be reassessed for each protocol. Ethical principals of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio. Senior leadership of each affected School has been notified.

Studies for which there is little to no direct benefit to participants
Study procedures involving in-person contact with participants at a location in the greater New York City (NYC) area or participant travel for research purposes within the greater NYC area must be paused, effective immediately or as soon as can be implemented. Procedures such as telephone contact or monitoring or remote data collection if part of such studies may continue.

Studies for which there is direct benefit to participants
These studies may continue. To the extent possible, study activities that can be done remotely by telephone or electronically should be done in this way.

No regulatory requirement for IRB Modification to pause research protocols or activities
Protocols or components of protocols may be paused without a formal protocol modification process.

Classification of protocols as providing direct benefit or not providing direct benefit
Please complete the Qualtrics survey which will be sent to you. This will help assess whether certain research activities should continue for your protocol. If you indicate your study should continue with in-person participant contact, or participant travel within the greater NYC area, the IRB will review and make the final determination regarding continued participant contact.

It is essential that you complete this survey as soon as possible, no later than close of business on Friday, March 13, 2020. Please click on the link to Qualtrics survey below and respond to the questions related to your protocol.

Resuming Activities
The IRB must be notified and permission by the IRB given prior to resuming any paused protocols or activities.

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