

TO

FROM

March 13, 2020

To whom this may concern,

Due to COVID-19 uncertainty, Drs. Karen Antman and Ravin Davidoff, the Institutional Officials at Boston University Medical Campus and Boston Medical Center, have determined that most research activities involving in-person interactions with subjects MUST STOP as of March 12, 2020 until further notice. The only exceptions are if canceling or postponing the activities would either (A) increase the risk to the subject’s safety or wellbeing or (B) deprive the subject of potential direct benefit. This is being done to protect research subjects.

Ongoing research with enrolled subjects must cease face-to-face interactions, unless the visit falls into one of the two exception categories noted above. The PI may explore alternative virtual visits in consultation with the sponsor or funding source, IRB of record, and coordination with the study subject. All study protocol deviations must be submitted to the IRB of record, according to that IRB’s policies for reporting. Each study team should contact their study subjects to explain the rationale behind the change in events.

Most studies must stop enrolling new subjects. The only exceptions would be studies where there is no direct subject contact (e.g., on-line only) and studies with the potential for direct benefit, that is, benefits that are not available through standard of care.

The IRB will continue to review and approve IRB applications for human subject research. For studies that are approvable, but do not meet the above new enrollment exceptions, the IRB will approve the study but explicitly note that enrollment cannot start until the pause in clinical research activities is lifted.

We appreciate your patience with this matter and recognize this is not ideal for data collection, but as always, our patient’s safety is our first priority. As a possible result to this COVID-19 response, we would like to ask that you think about how large volumes of deviations could best be managed, and look forwarding to finding out how we can help mitigate the complexities of our unpredictable circumstance. We will follow-up with you when we have an expected timeline for returning back to regular clinical research activities.

We have provided a variety of contacts, please feel free to reach out with any questions:

**BMC/BUMC IRB**: medirb@bu.edu

**BMC Research Operations**

* Grants and Contracts: Grants.Admin@bmc.org
* Clinical Trial Office: ClinicalTrialOffice@bmc.org

FROM