

TO

FROM

March 16, 2020

To whom this may concern,

Due to COVID-19 uncertainty, the Institutional Officials at the Medical University of South Carolina are limiting clinical study activities that require the presence of non-clinical personnel in acute care settings. This includes study activities in inpatient units and emergency departments. Additionally, enrollment into new studies must be suspended (as of March 16, 2020) until further notice. The only exceptions are if (A) canceling or postponing study activities would increase the risk to the subject’s safety or wellbeing, (B) the study provides life-saving therapies, or (C) the study specifically addresses COVID-19. This mitigates risk to both research subjects and MUSC staff.

Ongoing research with enrolled subjects must cease or limit face-to-face interactions to the extent possible, unless the visit falls into one of the three exception categories noted above. The PI may explore alternative virtual visits in consultation with the sponsor or funding source and IRB of record, in coordination with the study subject.

MUSC is discouraging recruitment of new research participants, thus 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 of life-saving therapies or studies specifically for COVID-19. All studies that are currently in the start-up phase will continue to move toward study activation.

MUSC currently has visitor restrictions. Therefore all study monitor visits will need to be postponed or conducted remotely until further notice.

The MUSC IRB will continue to review and approve IRB applications for human subject research. However, initial applications will be contingently held until COVID-19 recruitment restrictions have been lifted.

We appreciate your patience with this matter and recognize this is not ideal for data collection, but as always, patient and staff safety is our priority. As a possible result to this COVID-19 response, we would like to ask that you think about how to manage remote visits and large volumes of deviations and we look forward 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.

Please feel free to reach out with any questions. Attached is a list of questions which will help our team to quickly mobilize to remote study visits during this time.

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