Memo: COVID-19 Study Related Issues

★ This memo applies only to COVID-19 related issues resulting in a deviation from the protocol.

Date: March 13, 2020

Pennington Biomedical Research Center continues to closely follow the Coronavirus Disease 2019 (COVID-19) outbreak.

The IRB is providing the following guidance:

- The IRB has developed interim measures to protect research participants and staff during the COVID-19 outbreak which may involve deviating from approved study procedures prior to securing IRB approval. To streamline the process of tracking COVID-19 related deviations to protocols and notifying the IRB, we have created specific ***COVID-19 related tracking logs*** to cover some protocol deviations without requiring a formal modification approval by IRB. These logs will be required to be sent in *bi-weekly* (instructions will be provided on the logs) to be kept up to date on all COVID-19 related protocol deviations.
    a. *Examples of deviations include*, but are not limited to, cancelling or postponing non-essential study visits, conducting phone visits in lieu of in-person visits, conducting safety screening prior to in-person visits occurring, shipping investigational products directly to participants, or other changes as deemed appropriate to eliminate immediate hazards to subjects because of the risk of exposure to this highly communicable disease.
    b. If it is anticipated that immediate changes made to the study to eliminate apparent immediate hazards will be sustained for a duration that would practicably allow for an amendment to cover such changes, then the investigator/sponsor should seek approval of a protocol amendment by the IRB. If there is any question about whether a protocol amendment is needed, please contact the IRB for guidance.
    c. If a temporary hold or suspension of research is necessary due to PBRC closure or at the discretion of the investigator, a note to file may be submitted in IRB Manager. The note must explain the changes being made and provide enough information for the IRB to assess the relative risks resulting from the changes.
        - Investigators conducting FDA-regulated research involving an IND or IDE must contact the FDA if he/she is the holder of the IND/IDE.
    d. If the sponsor closes the study or there is a change in status, a note to file must be submitted per our normal practices.
    e. *For industry studies*, consult with the sponsor before making any changes or deviating from study procedures.
    f. We are working on an ***institutional participant letter regarding COVID-19*** to be sent to all active study participants through RCG. If you have a letter created by the sponsor, or have a study-specific letter you wish to be sent out in addition to the PBRC generic letter, please submit this as subject materials to be approved by the IRB.

If you have questions or concerns, please consult the IRB staff.