Please see below guidance from WIRB. For studies in which Upstate is the IRB of record, the same guidance applies.

Changes to Research Made in Response to COVID-19

WIRB-Copernicus IRB has received questions from several research sponsors about the appropriate process for making changes to clinical studies in response to the current COVID-19 epidemic. These changes may include things like:

- Decreasing the number of protocol-mandated in-person study visits to healthcare facilities
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine, allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

We want to provide information on the requirement for IRB review of changes in research made in response to this situation.

The FDA regulations require that:

Each IRB shall … (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. 21 CFR 56.108(a)(4).

If a sponsor or investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported to the WIRB-Copernicus IRB within 5 days, as per WCG policy. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine because of suspected or known exposures. WCG encourages sponsors and investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants.

The notification to the IRB may be a full protocol amendment, but it does not have to be. The notification of the change in research (CIR) plans may also be a memo, letter, or other document that explains the changes being made, and provides enough information for the IRB to assess the relative risks resulting from the changes. The amendment or CIR document will proceed through IRB review as per the usual process. When the IRB of record is Upstate, pleases submit to the Upstate IRB, via IRBNet.

If you have questions, please contact your WIRB-Copernicus IRB representative, or Client Services, and they will be able to connect you with a member of our regulatory, medical or compliance teams as needed. When the IRB of record is Upstate, please contact benedicm@upstate.edu

March 12, 2020