Salus IRB

March 12, 2020

To: Salus IRB Clients

Re: COVID-19

Salus IRB Office
Our office is open and is fully operational. Our team has the capacity to work remotely, if necessary, and IRB meetings are conducted online.

Research Sites
Keeping abreast of information provided by relevant government agencies, investigators should consider how COVID-19 might impact their ability to conduct their study protocols and plan for any changes that might need to occur due to potential unavailability of study participants and/or study personnel because of illness or the ability to conduct certain study-related procedures which may pose increase risks to study participants.

Investigators may take precautionary measures such as screening research participants by phone for COVID-19 before any scheduled study visits. This screening procedure **does not require IRB approval**.

Study Change Considerations
Investigators may be considering the following changes to ongoing studies:

- Minimizing person-to-person contact by decreasing the number of mandated in person study visits
- Replacing in person study visits with home visits (for simple procedures) or allowing study procedures at alternate locations, i.e., blood draws at an alternate lab
- Shipping investigational products directly to research participants
- Considering remote options for procedures such as questionnaires, surveys, screening, or consenting
- Considering a temporary halt in study conduct due to staff availability, participant safety, or for other reasons

For studies involving investigational products, investigators should work closely with the study sponsor and the IRB to ensure subject safety.

IRB Approval or IRB Notification of Study Changes
Any change made to the research protocol still needs to be reviewed by the IRB except for the incorporation of mandatory COVID-19 screening.

Changes to IRB-approved research procedures require IRB approval before being implemented "except where necessary to eliminate apparent immediate hazards to the human subjects" 45 CFR § 46.108(a)(3)(iii); 21 CFR § 56.108(a)(4).

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If the investigator makes a change to the research to eliminate immediate harm, notify the IRB within 10 business days (or 5 days for device research). Report the change on *Form 300*.

We will consider the review of changes due to COVID-19 a priority.

We will provide additional updates as necessary.

If you have any questions, please contact us at 512.380.1244 or salus@salusirb.com.