Salus IRB

January 20, 2022

To: Salus IRB Clients

Re: Salus IRB Policy Statement in Response to the COVID-19 Pandemic Update

In accordance with the guidance entitled, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic," issued on March 18, 2020, which allows for IRBs to create new or change existing policies for reviewing study modifications due to COVID-19 illness and/or COVID-19 control measures, Salus IRB issues the following policy exception statement.

Ensuring research participant safety in implementing review procedures is our primary goal. A secondary goal is to minimize the burden on sponsors, investigators, and research staff by providing exceptions to existing policies regarding IRB notification requirements. It is in this spirit, that Salus implements a policy exception specifically for those clinical trials impacted by COVID-19. This policy remains in effect until further written notice from the executive director.

Deviations to eliminate apparent or immediate harm:

Typically, changes in a protocol are not implemented before review and approval by the IRB. However, when urgent or emergent study changes (protocol or informed consent) are anticipated to minimize or eliminate immediate or apparent hazards to research participants or research staff (i.e., to limit exposure to COVID-19), such changes may be implemented without IRB approval.

Research participants must be notified of changes to the study and monitoring plans that could impact them. Notification of study changes may be accomplished by letter, email notification, or other method.

IRB notification of these changes must be submitted to the IRB within a reasonable time after the change was made up to 90 days.

The notification may be submitted by memo, formal letter, protocol amendment, or other study documentation provided the notification includes enough information to allow for IRB assessment. Depending on the nature of the changes, the IRB may require a formal protocol amendment after initial review of the notification.

Deviations that do not impact the safety of research participants:

Minor deviations that do not pose increase risk of harm to research participants are not required to be reported to Salus IRB. This is in accordance with Salus' current policy.

If the investigator is required to report minor deviations to the IRB, the notification may be submitted by memo, formal letter, or on Salus IRB Form 320.

Other IRB reporting requirements that have been impacted by COVID-19:

Provide a written notice to the IRB to include as much detail as possible explaining how the IRB reporting requirement has been impacted. The IRB is afforded some flexibility in reviewing such items and each submission is considered on a case-by-case basis.

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