Alpha IRB

1011 Avenida Pico, Suite C 497. San Clemente, CA 92673
T: 949-542-3882 F: 949-940-0134

www.alphairb.com

MEMORANDUM

Date: March 18, 2020
Re: Alpha IRB Response to COVID-19 Pandemic

Alpha IRB would like to provide guidance and reassurance to Sponsors, CROs and investigators in consideration of the COVID-19 pandemic.

We understand that, due to the quickly evolving public health emergency, modifications to your current IRB approved research may be necessary. Some of these changes may include:

- Alternative methods for in-person study visits (telemedicine, home visit, alternative location for specific assessments or labs)
- Shipping investigational products directly to research participants (consult with Sponsor and FDA)
- Implementing remote monitoring processes/programs in lieu of on-site monitoring

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).

As such, any proposed change to be taken in response to the COVID-19 pandemic must be reviewed and approved by Alpha IRB prior to implementation; except where necessary to minimize or eliminate immediate hazards or to protect the life and well-being of research participants. We encourage Sponsors, CROs and investigators to work with Alpha IRB as early as possible when changes to research are being considered.

Requested changes to research may come in the form of a formal protocol amendment, if applicable, or may be submitted as a memo or letter which describes the changes to be implemented. The review of the document/information will go through the normal IRB review process.

If it is necessary to make a modification to the research without prior IRB approval in order to eliminate immediate hazards to research participants, these changes can be made and then reported to Alpha IRB promptly, but within 10 business days.

Just to also briefly address the status of Alpha during this time - there are no planned changes to Alpha IRB's process, timelines or procedures. Alpha's IRB panel meets remotely, and IRB key staff have the ability to function remotely, whenever necessary. Therefore, Alpha IRB's operations reviews are continuing to run without interruption through the COVID-19 pandemic.

Alpha IRB staff are available to assist you. Please feel free to reach out to your Study Management Specialist directly, or call 949-542-3882 or email info@alphairb.com with any questions.

Please also review FDA's recently published guidance in response to the COVID-19 pandemic:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic