Key Points from FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic (March 2020)

The following information is a summary of the FDA guidance for your convenience. The full guidance contains ADDITIONAL FAQs, so please click the link above to see the full guidance.

Due to the COVID-19 pandemic, FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Top priorities for FDA-regulated studies are: assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity. Remember all changes to study design, consent platforms, drug delivery, etc. require submission of an Amendment to the IRB.

- Participants must be kept informed of changes to the study & study visits that could impact them.
- Sponsors may decide that the protection of participants' safety, welfare, and rights is best served by continuing study participants in the trial per protocol or by discontinuing the administration of the investigational product. If the study cannot be properly conducted under the existing protocol, the sponsor may decide to stop ongoing recruitment or even withdraw trial participants.
- Sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment) could be used, and would be sufficient to assure the safety of participants.
- COVID-19 screening procedures (like those required at DUHS) do not need to be reported as an amendment to the protocol, unless the sponsor plans to use the data collected as part of a new research objective.
- Changes to the protocol to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be done without prior IRB approval or before filing an amendment to the IND or IDE. However, these changes must be reported to the IRB and FDA afterwards.
- A listing of all participants affected by the COVID-19 related study disruption by unique subject number identifier and by investigational site, and a description of how and for how long the individual's participation was altered, must be documented.
- Missing protocol-specified information, such as missing study assessments or missing endpoints, should be fully documented in the case report form, including the relationship to COVID-19.
- If scheduled visits at clinical sites will be significantly impacted, certain investigational products may be sent to participants using a secure delivery method. Consult with the Sponsor or FDA review divisions on plans for alternative administration of investigational products.
- FDA will allow investigators to obtain a signed informed consent from a patient who is in isolation, by alternate methods such as electronic consent, telephone consent or video conference with the presence of an impartial witness, or a photograph of the signed informed consent document.
- If the patient is unable to provide informed consent and there is a legally authorized representative (LAR), investigators must obtain consent from the participant's LAR in accordance with 21 CFR 50.27(a).