COVID-19

COVID-19 AND RESEARCH AT DUKE

The DUHS IRB and Duke University School of Medicine Administration (DUSOM) wish to assure the Duke research community that the safety of research participants and study teams is paramount during the COVID-19 outbreak. Because information and processes involving the outbreak are quickly evolving, please monitor the Duke COVID-19 Resource page and expect further notifications from Duke Health, Duke University, DUSOM, and/or the DUHS IRB.

Click Here for the "Updated IRB Guidance on Changes to Consent Process during the COVID-19 Pandemic" dated September 8, 2020. This document provides further guidance from the DUHS IRB regarding the need for an amendment when changes are made to the consent process or platform.

Click Here for the new policy on "COVID-19 and Consent for Research at Duke" dated April 30, 2020. The purpose of this policy is to provide guidance from the DUHS IRB to Duke's research community regarding the consent process during the COVID-19 pandemic.

Click Here for the full memo sent out to the DUHS research community regarding COVID-19 and Research at Duke on March 11, 2020.

Click Here for common examples of when to submit an Amendment to the IRB, given current COVID-19 considerations.

FDA Issues Updated Guidance on Clinical Trial Conduct During the COVID-19 Pandemic

On September 21, 2020, FDA amended their guidance: FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic?.

Click Here for DUHS IRB's summary of changes to the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic? that was revised on September 21, 2020. This document is not to be considered a summary of all changes to the guidance but only representative of the most relevant changes.

Click Here for highlighted version showing the changes in the September 21, 2020 version.

Click Here for a link to the FULL FDA Guidance.
Click Here for the One-Page Summary of FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 2020)

The FDA has established an email address for questions regarding clinical trial conduct during the COVID-19 pandemic: Clinicaltrialconduct-COVID19@fda.hhs.gov.