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 March 18, 2020, FDA issued FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic to provide general considerations to assist sponsors and others in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic. On March 27, 2020, FDA amended the guidance to include an appendix to further explain those general considerations by providing answers to questions about conducting clinical trials that the Agency has received during the COVID-19 pandemic. For the updated guidance, please see: https://www.fda.gov/regulatory-information/search-fda-guidance-documents...

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

Click Here for the One-Page Summary of FDA Guidance on Conduct of