

The purpose of this communication is to apprise Duke researchers of the changes in the updated FDA Guidance entitled “*Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency*” issued on September 21, 2020. Duke investigators and study personnel are strongly advised to read the guidance in its entirety. The information below is not to be considered a summary of all changes to the guidance but only representative of the most relevant changes. A copy of the revised guidance in its entirety can be found on the IRB’s website at: <https://irb.duhs.duke.edu/node/4722> .

This guidance applies only to FDA-regulated studies, regardless of funding source.

I. The Consent Process

The FDA requirement for a signed consent form is unchanged. However, the revised guidance offers additional methods for documenting valid consent when the traditional discussion and provision of the subject’s signature or eConsent is not possible. Please refer to Q10 in the revised guidance for different scenarios and details.

When a participant cannot travel to a trial site for consent and eConsent is not possible, the revised guidance provides for return of the signed document via fax, secure email of a photo, or posting to a secure internet address. Please refer to Q11 in the revised guidance for details.

When a participant cannot print and sign, or electronically sign, a copy of a consent form that has been provided electronically, the revised guidance offers seven new options for documenting consent. Please refer to Q12 in the revised guidance for details.

Please be advised that the DUHS IRB will NOT approve Item #4 under Q12 (signature on a blank piece of paper) as a means of documenting consent. All other methods detailed in the guidance are acceptable.

II. Amendments and Deviations resulting from the COVID-19 Pandemic

The revised guidance defines the documentation required for conducting study visits remotely because of the pandemic. Study teams should maintain a listing of all study visits that were completed remotely rather than at the clinical site as described in the IRB-approved protocol.

The listing should include the following:

- iRIS Pro#
- patient ID
- Date/purpose of visit

This listing should be included in the annual progress reports submitted to the DUHS IRB and FDA. Please refer to Q3 in the revised guidance for details.

III. Additional Topics

The revised guidance includes additional guidance not found in previous versions of the document. This guidance covers recommended best practices for remote study visits (Q20), reporting requirements for COVID-19 events occurring in studies that are not evaluating COVID-19 therapies (Q23), and investigator handling of sponsor IND safety reports (Q24). There is also additional guidance specifically meant for sponsors and NDA-holders(Q19/Q22).

Please contact your IRB analyst, the IRB Directors, or IRB Chairs if you need more information. Contact information can be found at: <https://irb.duhs.duke.edu/about-us/staff-and-chairs>