UPDATED IRB GUIDANCE ON CHANGES TO CONSENT PROCESSES DURING THE COVID-19 PANDEMIC
September 8, 2020

The purpose of this document is to provide further guidance from the DUHS IRB regarding the need for an amendment when changes are made to the consent process or platform. In its previous Consent guidance issued April 30, 2020, the DUHS IRB permitted specific changes to the consent process without formal IRB approval in order to immediately increase safety to both study teams and participants. With the research community now several months into revised consent processes driven by COVID-19, the DUHS IRB is requesting that study teams use the remainder of 2020 to formally submit amendments in iRIS to accurately reflect these changes, as outlined below.

As a starting point, please refer back to the original IRB document entitled *"COVID-19 and Consent for Research at Duke"* located at:
https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/field/attachments/COVIDandCONSENTFINAL_4_30_2020.pdf

As stated in the April 30, 2020 guidance cited above, please keep in mind that OHRP and FDA requirements for waiver of consent or waiver of documentation of consent have not changed during this pandemic. Waiver requests must still be consistent with applicable federal regulations and obtain DUHS IRB approval prior to implementation. For **all** studies, changes to either the IRB-approved consent language or the signature requirement will require IRB approval prior to implementation.

I. Definitions

For the purposes of this document, the following definitions will be used:

"eConsent", as per the FDA and OHRP definitions, means the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

"FDA-regulated" means research involving human subjects where one of the purposes of the study is to evaluate the safety and/or efficacy of a drug/device/biologic, regardless of whether or not the study is being conducted under an IND/IDE/BB-IND. Please be reminded that software algorithms developed with the intent to influence therapeutic decisions or clinical care may be considered devices under FDA regulations.

"Platform" means the method by which the consent form is presented. For example, the platform can be paper, email, RedCap, etc. Platform does not include the IRB-approved language in the consent document or the signature method.

II. FDA-regulated Studies

FDA-regulated studies require an amendment approved by the IRB to change platforms (e.g., paper to eConsent). The purpose of this requirement is to ensure that the change maintains compliance with FDA regulations governing valid consent. **If an FDA-regulated study has been moved to eConsent**

without formal IRB approval, please submit an amendment to the IRB as soon as possible to bring your application up to date.

III. Non FDA-regulated Studies

a. Greater-than-Minimal Risk Non-FDA regulated Studies

Non-FDA regulated studies that are greater-than-minimal risk (having received a convened board review by the IRB) must submit an amendment and receive IRB approval prior to moving to an eConsent process. The purpose of this requirement is to ensure that this change is in compliance with OHRP guidelines regarding eConsent procedures and subject verification.

b. Minimal Risk Non-FDA regulated Studies

Non-FDA regulated studies that are minimal risk (having received an expedited review by the IRB) may move to eConsent, as defined herein, without prior IRB approval while COVID restrictions are still in effect. However, it is essential that study teams maintain a log of consent activity during this time should an accounting be required later. Once research returns to its pre-pandemic processes, study teams must obtain IRB approval if they wish to continue with revisions to platforms. The IRB will issue a research-wide notice once this stage is reached.

IV. Amendment Submissions to the DUHS IRB

The DUHS IRB is working to have all FDA regulated and non-FDA regulated studies that are greater-than-minimal risk revised to accurately reflect current consent processes and approved by the IRB by the end of calendar year 2020. In order to avoid inundating the IRB with amendments, study teams are encouraged to wait until a regular amendment needs to be submitted and simply combine the revision to the consent process with other needed changes into one submission. In all cases, the IRB encourages study teams to keep the previous paper consent process even if you are adding eConsent, so that either method may be used at the study team's discretion.

Whether a study team chooses to combine other revisions with the consent revision or not, please submit amendments to bring the consent process up-to-date for FDA-regulated studies and all non-FDA regulated studies that are greater-than-minimal risk to the DUHS IRB no later than **November 15, 2020**.

Please keep in mind that non-FDA regulated, minimal risk studies do not have to submit amendments at this time.

Please contact your IRB specialist or an IRB Chair/Director if you have further questions. Contact information for all IRB personnel can be found at: https://irb.duhs.duke.edu/about-us/staff-and-chairs

Thank you.