



## **POLICY STATEMENT REGARDING THE IRB APPROVAL STAMP ON CONSENT FORMS**

11/20/2023

The Duke University Health System Institutional Review Board (DUHS IRB) has determined that study subjects will review and sign a consent form that does not bear an IRB approval stamp and/or statement. It is the DUHS IRB's opinion that a visible IRB approval stamp on a consent form could be interpreted by the potential participant as an endorsement of the study by the DUHS IRB, and could thus unduly influence the participant in making an informed, objective decision regarding participation in the study.

With the IRB's electronic submission system (iRIS), the footer on the bottom of each page of the consent form serves as the IRB approval stamp or watermark. The footer is generated by the iRIS system when a Board Specialist/Analyst issues the command to stamp/watermark the consent form as the approved version. The footer contains the following information:

DUHS IRB

IRB NUMBER: Pro #

IRB REFERENCE DATE:

IRB EXPIRATION DATE:

The IRB Reference Date is the date on which the Board Specialist/Analyst issues the command to stamp/watermark the approved consent form. The consent form bearing that IRB Reference Date in the iRIS-generated footer is considered the IRB-approved version. The IRB-approved version of all consent forms must be free of tracked changes.

The following forms will bear the stamp/watermark when uploaded to the Informed Consent section within iRIS: consent forms, e-consent forms, electronic consent forms, and verbal consent forms. Studies that rely on an external IRB could have their consent forms stamped/watermarked upon request if the central IRB does not provide for a stamped form.

Previous Version Date(s): 8/12/2008, 8/19/2015, 9/28/2021