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Human Research Protection Program

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RE: Update to September 29, 2020 Memo about Electronic Research Consent Signatures and Electronic Research Records Management

Dear Principal Investigator,

This memo provides an update to the September 29, 2020 memo regarding the UCSF Human Research Protection Program's (HRPP) guidance on obtaining electronic consent and HIPAA authorization signatures for research during the COVID-19 public health emergency. This memo may be shared with study Sponsors.

The September 29, 2020 memo stated that UCSF's licensed versions of DocuSign and REDCap had not yet been validated for compliance with 21 CFR Part 11, and that the institution was working to bring both systems into FDA compliance.

The HRPP is pleased to announce that UCSF now has two versions each of DocuSign and REDCap: a standard version and an FDA-compliant version. Studies *not* regulated by the FDA may use a standard version to collect research signatures, while FDA-regulated studies should use an FDA-regulated version.

The FDA-compliant version of DocuSign is available to UCSF researchers now. The FDA-compliant version of REDCap for eConsent is being piloted with a limited number of studies and will be available to broader use once the pilot phase is complete.

Over the past year, UCSF has permitted researchers to use standard DocuSign and REDCap platforms to obtain electronic consent and HIPAA authorization signatures remotely for all studies (including FDA-regulated trials) continuing to enroll during the COVID-19 public health emergency. As of now, FDA-regulated studies that are still enrolling participants should transition to the FDA-compliant version of DocuSign or REDCap at the earliest opportunity. The HRPP understands this transition may not be immediate in all cases, as it may take some time to migrate your materials to the new version, and availability might be limited for a short time.

Please note: Already-enrolled participants do not need to be reconsented on the FDA-compliant version.

Please see FAQ #2 on the IRB COVID-19 FAQs & Resources website for more guidance.

Sincerely,

Edward Kuczynski, MA
Director, Human Research Protection Program