



University of California
San Francisco

**Human Research
Protection Program**

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May 28, 2020

RE: Guidance on Obtaining Electronic Signatures for Research Consent and HIPAA Authorization during the COVID-19 Public Health Emergency

Dear Principal Investigator,

This memo may be shared with research sponsors to document the Human Research Protection Program's guidance on obtaining electronic consent and HIPAA authorization signatures during the COVID-19 public health emergency.

The University of California San Francisco has issued an [Interim Policy on Human Subjects-Related Research Visits](#) outlining the conduct and location of research visits during the COVID-19 public health emergency. For the safety of research participants and investigators, many consenting procedures and study visits are being conducted remotely. UCSF has instructed all investigators to review and follow the joint FDA/OHRP guidance on obtaining electronic consent signatures in FDA-regulated research, [Use of Electronic Informed Consent in Clinical Investigations-Questions and Answers \(Dec 2016\)](#) and the [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency \(March 2020, updated May 14, 2020\)](#).

Implementation of the consenting procedures described in the above guidance documents may not be feasible in all cases, thus creating obstacles to study enrollment. In particular, electronic consent signature options are limited because UCSF's licensed versions of DocuSign and REDCap have not yet been validated for compliance with [21 CFR Part 11](#). We are actively working to bring both systems into Part 11 compliance, with REDCap validation expected to be completed by mid-June.

In the interim, based on review by UCSF Offices of Legal Affairs, Privacy, and Ethics and Compliance, we are permitting researchers to use either the DocuSign or 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. Please note that DocuSign and REDCap are the only electronic platforms that UCSF researchers may use to obtain electronic consent and authorization signatures during the Interim UCSF Policy.

The [IRB COVID-19 FAQs & Resources](#) webpage offers guidance on obtaining electronic signatures for consent and authorization, including:

- Information about DocuSign and REDCap
- Risk mitigation measures to protect participants and the University
- Requirements for documenting the consent process ([45 CFR 46.117](#) and [21 CFR 50.27](#))

Sincerely,

Edward Kuczynski, MA
Director, Human Research Protection Program

