



University of California  
San Francisco

**Human Research  
Protection Program**

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September 29, 2020

**RE: Update to May 28, 2020 Memo entitled “Guidance on Obtaining Electronic Signatures for Research Consent and HIPAA Authorization during the COVID-19 Public Health Emergency”**

Dear Principal Investigator,

This memo provides updates to the [May 28, 2020 memo](#) regarding the UCSF Human Research Protection Program’s (HRPP) guidance on obtaining electronic consent and HIPAA authorization signatures during the COVID-19 public health emergency. This memo may be shared with study Sponsors.

While UCSF has implemented a [gradual return to in-person research procedures](#) since the issuance of the [Interim Policy on Human Subjects-Related Research Visits](#) in March 2020, many studies still conduct consent procedures and study visits remotely where possible for the safety of research participants and research study teams. As such, there remains a widespread need to obtain electronic signed consent and HIPAA authorization for these studies. There is also a growing need for electronic transmission of other regulatory study documents, such as the Form FDA 1572, and for a comprehensive software platform for study management that is fully compliant with FDA regulations for electronic records.

The May 28, 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 has the following updates on the validation processes:

1. **REDCap eConsent:** Validation is well underway, with an FDA-compliant version expected to be available in mid- to late-December.
2. **DocuSign Part 11 Module:** Validation is just getting underway, with an expected availability date for an FDA-compliant version also by December.

Though Part 11 compliance validation is not yet complete, UCSF is 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.

In addition, UCSF has authorized use of two third-party platforms for obtaining Part 11 compliant electronic consent:

3. **SecureConsent:** This consent platform may be made available by the study sponsor for specific FDA-regulated studies.
4. **FDA COVID MyStudies:** Investigators conducting studies with an IND or IDE may request use of this platform for obtaining consent using a mobile device.

Also, UCSF is in the process of obtaining access to a third-party system for managing all study records:

5. **REDCap Cloud:** This system is fully FDA-compliant for electronic records and electronic signatures, and is currently being made available to researchers requiring such a comprehensive platform.



Additionally, researchers may use DocuSign for signing and transmitting FDA-regulated documents requiring signatures, such as Form FDA 1572 and financial disclosure forms, until such time as the DocuSign Part 11 module has been fully validated for use.

The [IRB COVID-19 FAQs & Resources](#) website is continually updated with this information for researchers.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward Kuczynski". The signature is fluid and cursive, with a long horizontal stroke at the end.

Edward Kuczynski, MA  
Director, Human Research Protection Program