

Statement on University of California, San Francisco Compliance with 21 CFR Part 11

University of California faculty and staff sometimes use electronic applications to maintain records and create signatures necessary to support human research activities, some of which are governed by FDA regulations.

Sponsors occasionally request certification of compliance with 21 CFR Part 11 (“Part 11”) or alternatively certification that systems covered by Part 11 will not be used for these activities. This notice provides information about the University’s use of electronic applications and the compliance of those systems with Part 11 requirements.

UCSF believes that its 21 CFR Part 11 Instance of DocuSign and its REDCap Premium platform together with the University’s electronic authentication system, is substantially compliant with Part 11 requirements and neither the University’s institutional review board nor, to our knowledge, any individual University researcher functioning as a sponsor and/or investigator has been cited for non-compliance with Part 11. However, the University is unable to provide any absolute representation or warranty of compliance.

Sponsors or others seeking certification of compliance may be provided with a copy of this letter. UCSF researchers performing FDA-regulated studies may rely on this substantial compliance certification or may print out and physically sign required documents and maintain these with other required research records. FDA has specified that it will exercise “enforcement discretion” where electronic records and signature are committed to physical writings and appropriately countersigned to assure security and non-repudiation.

Questions about this statement may be directed to: Joan Doherty, JD, Director, Office of Ethics and Compliance.

Attachment:

Statement of Brian Smith, JD, MBA, Chief Ethics and Compliance Officer / Senior Associate Vice Chancellor – Research on non-repudiation of electronic signatures in the DocuSign Part 11 Module and the REDCap Premium Software Platform

**Statement of Brian Smith, JD, MBA
on Non-Repudiation of Electronic Signatures in the
DocuSign Part 11 Module and the REDCap Premium
Software Platform**

To: Members of the University of California, San Francisco Research Community
From: Brian Smith, JD, MBA, Chief Ethics and Compliance Officer / Senior Associate
Vice Chancellor - Research
Re: Non-Repudiation of Electronic Signatures
Date: May 18, 2021

Researchers and research staff who are involved with FDA-regulated studies are asked from time to time to certify compliance with 21 CFR Part 11 (“Part 11” for short) – the regulations promulgated and enforced by FDA on the development, implementation, and use of electronic records and signatures.

UCSF Information Technology has reviewed UCSF’s 21 CFR Part 11 Instance of DocuSign and its REDCap Premium platform and validated that they are substantially compliant with Part 11 requirements. One of those requirements is the submission to FDA of a letter promising that any electronic signatures obtained using these platforms are intended to be the legally binding equivalent of hand-written, or “wet,” signatures. A copy of the letter we have submitted to FDA is attached for your information.

A variety of University policies and procedures require faculty and staff to secure their usernames and passwords (“ID/PW”) against unauthorized use. It is important to remember that any submission to the 21 CFR Part 11 Instance of DocuSign or to REDCap Premium using your ID/PW is assumed to be a submission by you personally. Because the signature is legal and binding, it is critical for you to comply with UC policies and assure the integrity of your ID/PW. Simple steps you can take to do so include:

- Never, ever share your password with anyone, including family members, students, supervisors, support staff, or others.
- Never keep your password in a computer file, on your desk, or in other obvious or easily accessible locations.
- When developing passwords, do not use dictionary words, foreign words, simple transformations, repeated words, names of people, keyboard sequences, phone numbers, or words with vowels removed, even if the system might allow this. Do use a line from a song or verse together with mixed cases, punctuation marks, and numbers (e.g., “Mary had a little lamb” would convert to m!h!a!!!! or m1h3a5171 or, best yet, M!h1!!!).
- Change your password frequently, at least every three (3) months, even if not prompted or required to do so by the system