

Statement on University of California, Irvine Health (UCIH) Epic Electronic Health Record System Compliance with 21 CFR Part 11

UCI Health 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 C.F.R. 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 EPIC Electronic Health Record System (EHR) with Part 11 requirements.

EPIC Electronic Health Record System is ONC Health IT certified. The FDA has stated that “use of such certified EHR technology is encouraged and, if used, would give FDA confidence during inspections that the EHR data is reliable and that the technical and software components of privacy and security protection requirement have been met.”

In addition, based on an internal analysis, there are no known issues that currently suggest that UCI Health’s EPIC Electronic Health Record System together with the University’s electronic authentication system, is not 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.

The FDA has not published certification criteria or a certification process for Part 11. Moreover, the FDA Guidance for Industry on Electronic Source Data in Clinical Investigations (September 2013) states, “**The FDA does not intend to assess the compliance of EHRs with Part 11.**” As a result of this guidance, EPIC has no plans to certify their EHR to Part 11. Given the lack of specific detailed certification criteria, the FDA’s own industry guidance, and Epic’s position with respect to the FDA Guidance, the University is unable to provide any absolute representation or warranty of compliance to Part 11.

The UCI Health Compliance, Risk, Information Security, and Privacy (CRISP) board believes that UCI Health’s EPIC system is compliant with Part 11 requirements.

Sponsors or others seeking certification of compliance may be provided with a copy of this letter. UCI researchers performing FDA-regulated studies may rely on this compliance statement 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:

Sriram Bharadwaj
UCI Health CISO
bharads1@hs.uci.edu

Attachment: Statement of on non-repudiation of electronic signatures in EPIC EHR System

Statement of Chief Compliance Officer On Non-Repudiation of Electronic Signatures in the EPIC System

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

The UCI Health Sciences CRISP Board has reviewed the internal analysis and believes that EPIC system is compliant with Part 11 requirements. One of those requirements is the submission to FDA of a letter promising that any electronic signatures used in EPIC are intended to be the legally binding equivalent of hand-written, or “wet,” signatures. A copy of the letter we are submitting 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 EPIC 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 UCI 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!h1ll!).*
- ◆ *Change your password frequently, at least every twelve (12) months, even if not prompted or required to do so by the system.*

Electronic Signature Certificate Statement

To Whom It May Concern:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that The University of California, Irvine Health intends that all electronic signatures executed in EPIC EHR System by our officers, directors, employees, students or contractors, located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures, subject to applicable University policies.

Sincerely yours,

Sriram Bharadwaj
UCI Health CISO
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