



Memorandum

OHSU Integrity Office
Mail code AD 140
3181 SW Sam Jackson Park Road
Portland, OR 97239-3098

August 6th, 2007

FROM: Ronald G. Marcum, MD
Chief Privacy Officer (CPO)
Chief Information Security Officer (CISO)
Chief Medical Information Officer (CMIO)

SUBJECT: Requests for Verification of OHSU Compliance with the Title 21 of the Code of Federal Regulations Part 11 (21 CFR Part 11)

Background

The United States Food and Drug Administration (FDA) issued regulations that establish criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed on electronic documents. The intent of these regulations is to permit the widest use of electronic systems while respecting the FDA's responsibility to promote and protect public health. As a result of these regulations, certain entities collaborating with OHSU may request that OHSU document compliance with these regulations.

Purpose

The purpose of this memorandum is to provide OHSU users with guidance for responding to inquiries regarding OHSU's compliance with 21 CFR Part 11. In many circumstances OHSU electronic information systems provide data that may be used in studies involving external parties (e.g., research sponsors). In the event that such an external party requests verification that OHSU information systems comply with 21 CFR Part 11, this document may be used as confirmation that the CISO has reviewed the capabilities of the LCR and Epic systems and verifies compliance with 21 CFR Part 11. Outside entities and OHSU users requiring further clarification regarding this guidance should contact the OHSU Integrity Office at ojps@ohsu.edu or (503)494-8849. The Integrity Office may respond to these requests by providing an overview of OHSU's relevant security controls established for the involved information systems. Generally, a detailed summary of OHSU's enterprise security program should not be necessary for any external party to collaborate with OHSU; however it is appropriate to represent OHSU's compliance with this regulation.

Guidelines

OHSU users may represent that OHSU's Lifetime Clinical Record (LCR) and EPIC systems are fully compliant with 21 CFR Part 11. Other OHSU systems may be compliant with this regulation, but such systems are beyond the scope of this memorandum. Information regarding 21 CFR Part 11 compliance of OHSU's electronic IRB system may refer to the relevant memorandum contained at <http://www.ohsu.edu/research/rda/irb/docs/policies/21cfr11.pdf>.

For additional questions, please contact the OHSU Integrity Office at ojps@ohsu.edu or (503)494-8849.