

University of Arizona Guidance Document

Statement Regarding Compliance with FDA 21 CFR 11 Electronic Records and Signatures

Electronic Medical Records

The Epic electronic health records (EHR) system in use at the University of Arizona Health Network (UAHN) are not owned, operated, or leased by The University of Arizona. Research contracts between The University of Arizona and industry sponsor partners are not contracts with UAHN. The EHR is property of UAHN, and not of the University. It is the position of The University of Arizona, based on compliance documents posted at the FDA website and consultation with legal counsel, that the EHR is part of the practice of medicine, and as such not regulated by FDA. The FDA “does not intend to assess the compliance of EHRs with part 11.”¹ As a result, The University of Arizona will make the following claims and information available to industry sponsor partners:

1. The EHR, per its manufacturer’s documentation, meets all requirements for Part 11 compliance.
2. The EHR has not been verified to be Part 11 compliant. The University of Arizona does not anticipate that this verification will occur, unless there are legal or regulatory changes that require such verification.

Electronic Signature Certification

The requirements for electronic signature certification, similarly being requested by industry sponsor partners with regard to the EHR, are part of 21 CFR 11. The FDA already has stated they do not intend to assess compliance of EHRs with part 11, and therefore electronic signature verification is not required for the EHR.

University of Arizona researchers are not authorized to sign electronic records or certification documents on behalf of the University of Arizona or UAHN.

Contact Information:

Please send questions relating to this guidance document to VPR-IRB@email.arizona.edu or 520-626-7575.

¹ Food and Drug Administration September 2013 Guidance for Industry Electronic Source Data in Clinical Investigations, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.