



EPIC Electronic Health Record System Compliance with 21 CFR Part 11

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The purpose of this statement is to provide UTHealth Houston investigators and research staff with guidance for responding to inquiries regarding compliance of Epic Electronic Health Record (EHR) system with part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (Part 11).

UTHealth Houston investigators and research staff conducting clinical trials sometimes rely on source documents created and maintained within Epic EHR system. This statement may be shared with sponsors when they request for certification of compliance of the EPIC EHR with Part 11 requirements.

FDA guidance released in September 2013, Guidance for Industry on Electronic Source Data in Clinical Investigations (<https://www.fda.gov/media/85183/download>) clarified that *"FDA does not intend to assess compliance of EHRs with part 11."* The guidance further states that *"The performance standards for these computer systems may be regulated by other authorities"* and refers to 45 CFR Part 170, Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology.

The FDA guidance released in July 2018, Guidance for Industry on the Use of Electronic Health Record Data in Clinical Investigations (<https://www.fda.gov/media/97567/download>) reiterates that *"Under the ONC Health IT Certification Program, certified EHR technology would be in compliance with applicable provisions under 45 CFR part 170. EHR technology with certified capabilities generally has clear advantages, because many of the certification requirements are aimed toward ensuring interoperable data sharing and enabling processes to keep electronic data confidential and secure. In particular, all EHR technology certified under the ONC Health IT Certification Program is required to meet certain privacy and security protection requirements for an individual's health information (see 45 CFR 170.314(d)(1) through (8) and 45 CFR 170.315(d)(1) through (11)). FDA encourages the use of such certified EHR systems together with appropriate policies and procedures for their use."*

Epic has stated that they have no plan 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, UTHealth Houston is unable to provide any absolute representation regarding compliance of the Epic EHR with Part 11.

With respect to Epic EHR compliance with Part 11 requirements, UTHealth Houston makes the following claims:

1. The Epic Electronic Health Record system per its manufacturer's documentation, meets all requirements for Part 11 compliance.
2. 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."
3. The Epic Electronic Health Record system has not been validated to be Part 11 compliant however, there is no reason to believe that UTHealth Houston's Epic EHR together with the UTHealth IT policies and procedures for access and signatures, is not compliant with Part 11 requirements.
4. 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.

UTHealth Houston investigators and research staff may provide sponsors or others seeking certification of compliance a copy of this statement.

Questions about this statement may be directed to:

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