DocuSign Compliance with 21 CFR Part 11

Responsible Executive:	Sujatha Sridhar, MBBS Associate Vice President, Research Compliance
Responsible Office:	Research Compliance
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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 DocuSign 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 use DocuSign for documenting informed consent obtained for participation in clinical trials. This statement may be shared with sponsors when they request for certification of compliance of the DocuSign with Part 11 requirements.

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

1. The DocuSign system per its manufacturer's documentation, meets all requirements for Part 11 compliance.
2. UTHealth Houston has reviewed the University's 21 CRF 11 compliant instance of DocuSign and together with the UTHealth IT policies and procedures for access and signatures we believe it is substantially compliant with Part 11 requirements. However, UTHealth Houston is unable to provide warranty of compliance.
3. 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 can be obtained by emailing clinicaltrials@uth.tmc.edu.

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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