Electronic Consenting (e-Consenting) Matrix

System/Application	e-Consent	Part 11 Compliant FDA-Regulated Research	e-Signature	Handwritten Signature	Mobile Compatibility
REDCap	X			X	
REDCap Part 11	X	X		X	
DocuSign	X		X		X
DocuSign Part 11	X	X		X	X
iMED Consent	X	X		X	X
Adobe Sign*	X	X	X		X

**UTSW does not use Adobe Sign*

Definitions:

e-Consent: Management of documentation electronically. Electronic consent (e-consent) is a process of obtaining informed consent from research participants using electronic methods, such as online forms or digital signatures, instead of paper forms.

21 CFR Part 11: 21 CFR Part 11, a section of the Code of Federal Regulations, outlines the FDA's guidelines for using electronic records and signatures. Set of FDA regulations, outlines requirements for ensuring the trustworthiness, reliability, and equivalence of electronic records and signatures to paper records and handwritten signatures in FDA-regulated industries. FDA-Regulated research requires that electronic consenting comply with Part 11 requirements. This regulation applies to FDA-regulated products, including pharmaceuticals, medical devices, and biologics.

e-Signature: an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record. Where you click a button electronically to create your electronic signature (selection of pre-determined font styles). To be compliant electronic signatures must include: The printed name of the signer. The date and time the signature was executed.

Handwritten Signature: An electronic handwritten signature, or eSignature, is a digital representation of a person's handwritten signature, created by drawing it on a tablet or using a stylus, or by using a digital image of a handwritten signature, and is used to sign documents electronically.

Mobile Compatibility: Mobile compatibility refers to a website or application being viewable and usable on mobile devices, such as smartphones and tablets.

References:

- Part 11, Electronic Records; Electronic Signatures - Scope and Application, September 2003 Guidance for Industry
- Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, December 2016 Guidance for IRBs, Investigators, and Sponsors

Version 1.0 Dated 03/17/2025