

In Depth Comparison of REDCap and DocuSign for Electronic Consent

	REDCap	DocuSign
What it is	Platform for ensuring understanding of consent information and obtaining electronic consent signatures	Platform for obtaining electronic consent signatures
Review types that may use it	Can be used by exempt, expedited, or full board studies	Can be used by exempt, expedited, or full board studies
What must be submitted to the IRB to use the platform?	Use of REDCap eConsent MUST be approved by the VCU Institutional Review Board (IRB) prior to implementation as there are many settings and features that must be reviewed	Use of DocuSign is preferred to be approved by the VCU Institutional Review Board (IRB) prior to implementation
In-person or remote use	Can be used in-person (using the in person template settings) or for remote consent	Can be used in-person (using the In Person Signing settings) or for remote consent
Consent and HIPAA waivers	No waivers needed	No waivers needed
Interactive elements (videos, quizzes, hover text, etc.)	Uses interactive elements such as images, videos, narration, or quizzes to help educate and gauge comprehension	Uses a standard consent document that might contain charts, images, or tables. Generally does not use interactive elements.
Cost to study teams	No costs except if using Twilio	No costs
Document Retention	Automatically generates and auto-archives a PDF of the signed eConsent document within REDCap	Signed consent forms must be downloaded and stored in the study's files
Legal validity in U.S.	Signatures are legally valid due to identity verification procedures (access codes, security questions, etc.)	Signatures are legally valid due to identity verification procedures (account login)
Legal validity in other countries	May <u>not</u> be used to obtain consent from participants in other countries due to the complexities of international eSignature laws, local legal systems and electronic signature technology preferences	Potentially may be used to obtain consent from participants in other countries if the recipient's preferred language is supported by DocuSign and eSignatures have legal validity in the proposed country. Consult VCU Legal Counsel before using.
FDA-regulated research	May <u>not</u> be used for FDA-regulated research studies	FDA-regulated research studies must utilize VCU's Part 11 DocuSign platform instead of the regular platform
Children	May be used during the assent discussion with children; however, assent signatures may NOT be obtained using electronic signatures. The IRB must approve a verbal assent process.	May be used during the assent discussion with children; however, assent signatures may NOT be obtained using electronic signatures. The IRB must approve a verbal assent process.
Decisionally impaired adults	May be used during the assent discussion with decisionally impaired adults; however, assent signatures may NOT be obtained using electronic signatures. The IRB must approve a verbal assent process.	May be used during the assent discussion with decisionally impaired adults; however, assent signatures may NOT be obtained using electronic signatures. The IRB must approve a verbal assent process.
Legally Authorized Representatives	May be used to obtain consent from a Legally Authorized Representative (LAR)	May be used to obtain consent from a Legally Authorized Representative (LAR)
Translated consent documents	May <u>not</u> be used for translated consent documents because aspects of the signing module are only in English	May be used for IRB approved translated consent documents if the recipient's preferred language is known and supported by DocuSign
Short form consent documents in other languages	May <u>only</u> be used to sign short form consent documents for persons with limited English proficiency when an "image-based" REDCap template is used	May be used to sign short form consent documents for persons with limited English proficiency.

