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Joint Clinical Trials Office (JCTO)		

DocuSign Access, Usage, and Document Retention for 21 CFR part 11 electronic signatures

1. Purpose

This policy defines the expectations, and accountability for the use of the 21 CFR part 11 module of DocuSign.

2. Scope/Applicability

This policy applies to all departments, investigators and study teams conducting clinical research who use DocuSign for routing research documents for electronic signatures.

3. Policy

1. DocuSign accounts are accessed via WCM/NYP Single Sign On (SSO) to be utilized for WCM research-related activities. Documents that can be routed via the 21 CFR Part 11 compliant DocuSign system include Informed Consent Forms (eConsent) or regulatory documents including, but not limited to, protocols, 1572 forms, delegation logs or financial disclosure forms.
2. WCM/NYP faculty and/or staff routing documents for electronic signature must use the WCM/NYP enterprise module of DocuSign.
 - I. To request an account, send an e-mail to JCTODocuSign@med.cornell.edu with the following information:
 - a. Name
 - b. CWID
 - c. Department/Division
 - d. Will you be sharing templates with any existing DocuSign users?
 - e. Justification for use of DocuSign
 - II. WCM/NYP faculty and/or staff do not need to request an account in order to sign or initial received DocuSign documents/envelopes. External recipients will be prompted to create their own DocuSign account and do not need to request an account from JCTODocusign@med.cornell.edu.
3. Personal use or other utilization of the 21CFR part 11 module of DocuSign under WCM-accounts for non-WCM research related activities is not permitted.
4. Each department is responsible for ensuring their assigned DocuSign users are appropriately trained. DocuSign training, including demos and/or tutorials may be requested as needed via JCTODocuSign@med.cornell.edu
5. An electronic signature is the legally binding equivalent of the signer's handwritten signature. Therefore, all document fields must be attributable to the individual completing them. Record and signature falsification is prohibited.
6. Signatures are protected by the WCM/NYP SSO.

7. Study teams are responsible for obtaining IRB approval to use DocuSign for research subject-facing documents, as appropriate, prior to study activities.
8. All documents/envelopes in DocuSign are retained for one year. Study teams are responsible for downloading completed envelope documents, include the certificate(s) of completion, for their records during the retention period.
9. Questions related to this policy can be addressed to JCTODocuSign@med.cornell.edu

4. Related Documents

8/11/21 [DocuSign TWIST Presentation](#)
[DocuSign System Validation Memo](#)

5. Policy Authorization

DocuSigned by Alicia Lewis
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16 September 2022

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Date