eReg Guidance Document
Electronic Signatures

Contents

Yale Center for
Clinical Investigation

Acronyms

CV: Curriculum Vitae

EDC: Electronic Data Capture

FDA: U.S. Food and Drug Administration

IND: Investigational New Drug Application

IRB: Institutional Review Board

NTF: Note to File

SAE: Serious Adverse Event

SOP: Standard Operating Procedure

Signature Requirements

Signature requirements apply to contact credential documents and protocol documents. URLs and regulatory tracking items are not signed. Zipped files cannot be routed for electronic signature. The eReg User uploading the document will select from three signature requirement options (Table 1). In order to route protocol documents for signature, a start date (preceding staff participation and conduct of study) must be entered for the signer. See the Delegation of Authority guidance document and the eReg Learning Portal for more information on the Delegation of Authority Start Date.

Only one Signature Requirement type below can be selected for each protocol document. Additional signers can be added using the same signature type (either electronic or wet signature). It is recommended that eReg electronic signatures are used exclusively to ensure compliance.

Table 1: Signature Requirements

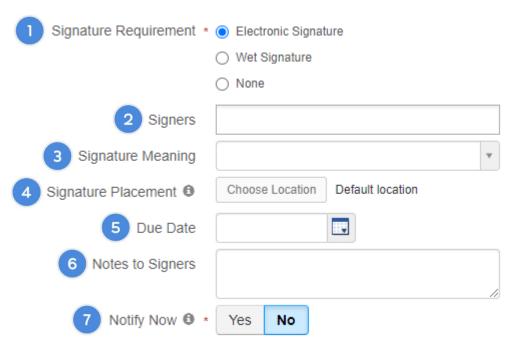| Signature Requirement	Use	Signature Placement
Electronic Signature	Select for documents to be routed for electronic signature within eReg. Only PDF files can be electronically signed. All information must be entered into the PDFs before being uploaded to eReg and routed for signature. See 'Use (Requirement)' column in Table 2.	Default Location or Custom Location*
Wet Signature	Select for documents signed in wet ink and/ or electronically signed outside of the eReg system. This requirement may be selected for documents including but not limited to: Delegation of Authority Log (paper) Investigational Product/ Device Documents	N/A

	Financial Disclosure Forms Other documents that have been digitally signed outside of eReg (ex. using Adobe Sign digital signature)	
None	Select for documents that are not signed and will not be routed for electronic signature within eReg.	N/A

* Default Location (appended to the last page of the document) must be used for documents that will be electronically signed by multiple staff. The Custom location can be used if the document requires one signature, such as a protocol signature page.
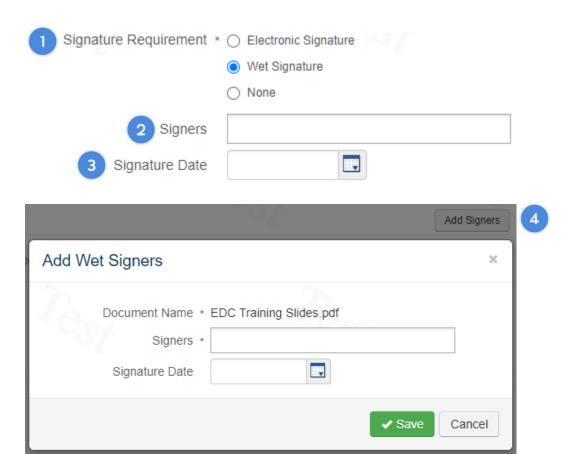
Electronic Signature

1: Select Electronic Signature for PDF documents to be routed for electronic signature within eReg (see Tables 1 and 2).

2: Select required signer(s). Protocol documents can be assigned based on all active protocol staff, by staff role, or by specific protocol staff members. See the eReg Learning Portal for further details.

3: Select appropriate signature meaning based on the type of document (see Table 2).

4: A signature location and optional date location can be specified after a single signer is identified and a signature meaning is selected. For documents requiring multiple signers, the signature placement must stay as Default location. See Table 2 and the eReg Learning Portal for further details related to placed signature requirements.

5: Select a due date (optional). See Table 2 for guidance related to signature due dates.

6: Enter a note directed to the signer(s) (optional).

7: Select Yes if the signer(s) should be notified immediately that a document is ready for their electronic signature. If No is selected, the signer(s) will not be notified immediately, but the document will display in their Sign Documents page. Please see the eReg Learning portal for additional information related to email notifications.

<u>Wet Signature</u>

1: Select Wet Signature for documents signed in wet ink and/ or electronically signed outside of the eReg system (see Table 1).

2: Select required signer(s).

3: Enter the date that the document was signed outside of the eReg system.

4: If there are multiple signers that signed the document on different dates, save each signer individually. Utilize the "Add Signers" button to add additional signers and signature dates.

No Signature Required (None)

1: Select None for documents that are not signed and will not be routed for electronic signature within eReg. There are no additional fields to complete.

Signature Meanings

A signature meaning is required when adding electronic signers. The type of signature meaning selected is dependent on the type of document being routed. See Table 2 for the list of signature meanings, associated messages, and examples of when to use each.

Table 2: Signature Meanings and Suggested Use

Signature Meaning	Message	Use (Requirement)	Signature Placement	Due Date
Approved	By electronically signing this document, I attest that I approve its content.	Curriculum Vitae (CV)	Default location	
		Delegation of Authority Log	N/A	Ensure protocol staff sign-off and PI sign-off on start dates and tasks is obtained before the staff person participates in the conduct of the study.
		Form FDA 1572	Custom location (Box 11 of the Form)	
		Investigator Agreement	Custom location	
		Notes To File (NTF)	Default or Custom location	
		Study Specific Standard Operating Procedures (SOPs)	Default location	
Read and Understood	By electronically signing this document, I attest that I have read and understood its content.	Protocol Training	Default or Custom location*	Ensure protocol training is obtained before the study staff person participates in the conduct of the study.

Yale Center for Clinical Investigation

		Electronic Data Capture (EDC) Training	Default or Custom location*	Ensure training is documented before the staff person uses the EDC system.
		Other Protocol Specific or System Training	Default or Custom location*	Ensure training is documented before the staff person uses the system.
Reviewed	By electronically signing this document, I attest that I have reviewed its content.	Investigator's Brochure Receipt Page	Custom location	Contemporaneous to receipt of the Investigator's Brochure.
		Protocol Signature Page	Custom location	Contemporaneous to receipt of the protocol.
		IND Safety Reports	Default location	Contemporaneous to notification of the safety event.
		SAE Reports	Default location	Contemporaneous to notification of the safety event.

* Default Location (appended to the last page of the document) must be used for documents that will be electronically signed by multiple staff. The Custom location can be used if the document requires one signature, such as a training attestation that is specific to one team member.

Collecting Electronic Signatures for Protocol Training

The Staff Training section is used to organize training documentation for protocol training, EDC training, and other protocol specific or system training. The IRB-approved Protocol must be uploaded to both the Protocol section and the Staff Training section. The document is routed for electronic signature(s) from the Staff Training section only. Most training materials will be routed to multiple team members, so the default signature location must be used. If the training material will be reviewed and signed by only one staff member, 'Chose Location' can be used to specify the placement of the signature and date.

Collecting Electronic Signatures for Contact Credentials

Contact credentials (ex. CV) are routed for signature to the associated contact. The contact must be a system user to sign credential documents. Multiple signers cannot be selected, a signature meaning is not associated, and custom signature placement cannot be selected.

Yale Center for
Clinical Investigation

Additional Resources

- YCCI Training Slides - ISF
- eReg Guidance Document – Delegation of Authority
- eReg Learning Portal
- YCCI eReg website: https://medicine.yale.edu/ycci/researchservices/systems/ereg/