

### eReg Guidance Document Electronic Signatures

### Contents

Acronyms
Signature Requirements
Table 1: Signature Requirements2
Electronic Signature
Wet Signature4
No Signature Required (None)5
Signature Meanings
Table 2: Signature Meanings and Suggested Use       5
Choosing a Custom Location for an Electronic Signature
Collecting Electronic Signatures for Protocol Training10
Collecting Electronic Signatures for Contact Credentials11
Viewing and Editing Electronically Signed Documents11
Additional Resources

V5.0 22-Oct-2024 Page 1 of 12







#### 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 (organization documents) 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). Staff must be active on the protocol, per their Protocol Staff Start/Stop Dates, in order to receive and electronically sign the routed document. See the Delegation of Authority guidance document and the eReg Learning Portal for more information on dates in eReg.

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.

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)	N/A
	Investigational Product/ Device Documents	

#### **Table 1: Signature Requirements**





	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

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When choosing Electronic Signature, the system will request additional information to determine who the document is being routed to and what is the meaning of the signature. Note that only PDF documents can be signed, and all information must be entered into the form/document before being uploaded and routed for signature.

1	Signature Requirement *    Electronic Signature			
		O Wet Signature		
		O None		
	2 Signers			
	3 Signature Meaning	Ψ		
4	Signature Placement 0	Choose Location Default location		
	5 Due Date			
	6 Notes to Signers			
	7 Notify Now 🖲 🔹	Yes No		

**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.

V5.0 22-Oct-2024 Page 3 of 12







**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.

#### Wet Signature

<ol> <li>Signature Requirement *          <ul> <li>Electronic Signature</li> <li>Wet Signature</li> <li>None</li> </ul> </li> </ol>		
2 Signers 3 Signature Date		
Add Wet Signers	Add Signers	4
Document Name * EDC Training Slides.pdf Signers * Signature Date		
✓ Save	Cancel	

**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.

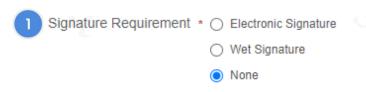
**4:** If there are multiple signers that signed the document on different dates, save each signer individually. Utilize the "Add Signers" button to add additional signers and signature dates.







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.

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 or Custom 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.
		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.

### **Choosing a Custom Location for an Electronic Signature**

If the document being routed for electronic signature requires one signature, the Signature Placement can be specified by clicking "Choose Location."





Create Document Vers	ion for Form FDA 1572_v3.0.pdf	×
Requirement *	Form FDA 1572	•
File *	Change Form FDA 1572_v4.0.pdf	- 1
Document Name *	Form FDA 1572_v4.0.pdf	- 1
Effective Date	01 Jan 1900	- 1
Valid Until		- 1
Comments		- 1
		- 1
Signature Requirement *	Electronic Signature	- 1
	O Wet Signature	- 1
	○ None	- 1
Signers	Kacey Richards ×	- 1
Signature Meaning *	Approved × v	- 1
Signature Placement 0	Choose Location Default location	- 1
Due Date		- 1
Notes to Signers		- 1
Notify Now 🙆 🗴	Ves No	-
	✓ Create	cel

To specify the Signature Placement location for a new document:

1: Locate the area of the document where you want to place the signature.

**2:** Adjust the text box until it appears how you want it. You can move it around in the area and change its height and width. If you want to remove the box from where you placed it, click the X to delete it.

**3:** Optional: Select Signature Date from the dropdown in the top of the window, to select the area of the document where you want to place the Date. Adjust the text box until it appears how you want it. You can move it around in the area and change its height and width. If you want to remove the box from where you placed it, click the X to delete it.

**4:** When the boxes are where you want them to appear on the signed document, click Save Location to return to the Create Document window.

V5.0 22-Oct-2024 Page 7 of 12

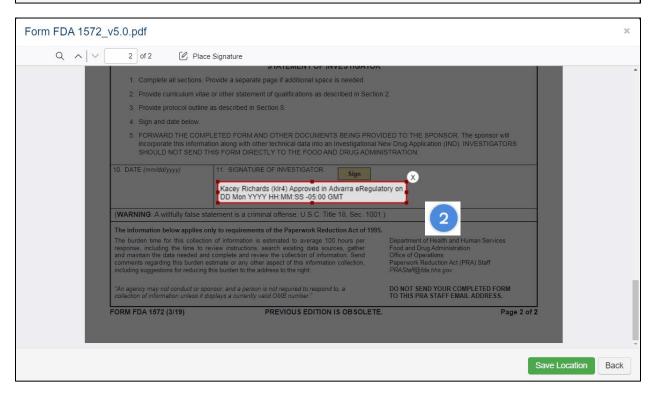




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## **GUIDANCE DOCUMENT** .

Form FDA 1572_v5.0.pdf					
Q ^   ~	2 of 2 X Cancel Placement				
		STATEMENT OF INVESTIGATOR		-	
	1. Complete all sections. Provide a sepa	rate page if additional space is needed.			
	2. Provide curriculum vitae or other state	ment of qualifications as described in Section	2.		
	3. Provide protocol outline as described	in Section 8.			
	4. Sign and date below.				
	incorporate this information along with	I AND OTHER DOCUMENTS BEING PROVI other technical data into an Investigational N RECTLY TO THE FOOD AND DRUG ADMIN	ew Drug Application (IND). INVESTIGATORS	3	
	10. DATE (mm/dd/yyyy) 11. SIGNAT	URE OF INVESTIGATOR Sign			
	(WARNING: A willfully false statement is a c	riminal offense. U.S.C. Title 18, Sec. 1001.	)		
	The information below applies only to requirem	nents of the Paperwork Reduction Act of 1995.			
	The burden time for this collection of information response, including the time to review instruction and maintain the data needed and complete and comments regarding this burden estimate or any including suggestions for reducing this burden to the	ns, search existing data sources, gather review the collection of information. Send other aspect of this information collection,	Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov		
	"An agency may not conduct or sponsor, and a per collection of information unless it displays a curren	rson is not required to respond to, a tly valid OMB number."	DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.		
	FORM FDA 1572 (3/19)	PREVIOUS EDITION IS OBSOLETE.	Page	e 2 of 2	
				Save Location Back	



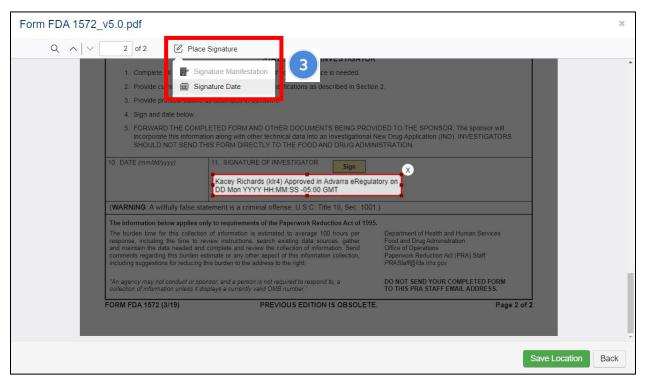


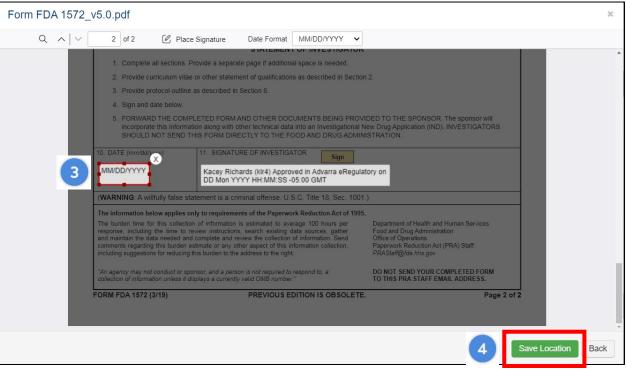
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## **GUIDANCE DOCUMENT** .





V5.0 22-Oct-2024 Page 9 of 12 •





The location of a placed signature can be adjusted on a protocol document <u>before</u> it is signed. The location of the signature cannot be changed after the document is signed in eReg.

1: View the Versions page for the document. If you've already specified a signature location, you'll see "(placed signature)" in the Electronic Signature Routing section.

**2:** Click on the link "[Name] needs to electronically sign (placed signature)" to see Electronic Signature Details.

**3:** Click Choose Location to specify a different location by following the workflow outlined in the Adding Electronic Signatures to Custom Location (previous slide).

4: After you've chosen a new location, click Save.

🞓 Protocols > 붵 YSM-GENERAL > 🎓 Regulatory Docu	ments > 🌓 Form FDA 1572	
Form FDA 1572 for YSM-GENERA	L	
Versions 1		+ New Version ▼
Form FDA 1572_v5.0.pdf		Actions -
Details File Form FDA 1572_v5.0.pc Effective Date 01 Jan 1900 Valid Until Comments Signature Requirement Electronic Signature Related Documents (0) >	Edit       Electronic Signature Routing         Image: Signature Signature Signature Signature Signature Details       Signer * Kacey Richards         Signature Meaning * Approved       Image: Signature Signature Signature Signature Signature Signer * Kacey Richards         Signature Meaning * Approved       Image: Signature Signature Signature Signature Signature Signer * Kacey Richards         Signature Meaning * Approved       Image: Signature Signature Signature Signature Signature Signer * Kacey Richards         Signature Meaning * Approved       Image: Signature Signature Signature Signature Signature Signer * Kacey Richards         Motes to Signer       Image: Signature Signer * Sig	Add Signers

#### **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

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V5.0

22-Oct-2024 Page 10 of 12







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## **GUIDANCE DOCUMENT**

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, and multiple signers cannot be selected. Custom signature placement can be used, and the signature meaning is pre-set to "Approved" for credentials.

#### Viewing and Editing Electronically Signed Documents

Electronically signed documents are viewed by the signer from the menu under their name:



When in a Protocol or Contact record, view a signed document within the version card by clicking the " icon. A new browser tab opens letting you know that the document is being generated. The signed document then appears in that tab when it's ready.

1	🞓 Protocols > 🚡 YSM-GENERAL > 🎓 Staff Training > 🚡 Protocol Training							
	Protocol_v6.0_202	4.01.09.pdf			Actions -			
	Details		Edit	Electronic Signature Routing	Add Signers			
	File	Protocol_v6.0_2024.01.09.pdf		Electronic Signatures Needed				
	Effective Date	09 Jan 2024		There are no electronic signatures still needed				
	Valid Until	15 Mar 2024		Electronically Signed				
	Comments			Jack Lance (tjl43)				
	Signature Requirement	Electronic Signature						
	Related Documents (0	)) >	Add Related Document	Sent Copies (0) >	Send Copy			

Once a document is electronically signed in eReg, the content of the document cannot be edited and the document cannot be deleted from the eReg binder. However, the Document Name can be changed after it has been signed:





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Protocol.pdf	ocument Name	
Details	- 62%	Edit
File	Protocol_v7.0_2024.03.15.p	df Document Details
Effective Date Valid Until	15 Mar 2024	
Comments		Requirement - Protocol Training File - Change Protocol v7.0 2024.03.15.pdf
Signature Requirement	Electronic Signature	Document Name - Protocol, v7.0_Approved 2024.03.15[pdf
		Effective Date • 15 Mar 2024
		Valid Until
\ <b>\</b> /		Comments

When the document name is updated, it is also updated on the signature manifestation page as well as the Signed Documents page.

	Document Name *	Protocol, v7.0_Approved 2024.03.15 pdf
	Effective Date *	15 Mar 2024 💽
	Valid Until	
	Comments	
Sigi	nature Requirement 🔹	Electronic Signature
		O Wet Signature
		O None

#### **Additional Resources**

- YCCI Training Slides ISF ٠
- eReg Guidance Document Delegation of Authority
- eReg Learning Portal
- YCCI eReg website: https://medicine.yale.edu/ycci/researchservices/systems/ereg/ •

