

eReg Guidance Document

Electronic Signatures

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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.

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

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

☐ Wet Signature

☐ None

2

Signers

3

Signature Meaning

4


Signature Placement ⓘ

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.





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

1 Signature Requirement * ☐ Electronic Signature
☒ Wet Signature
☐ None

2 Signers

3 Signature Date

4 Add Signers

Add Wet Signers

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.





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 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 Version for Form FDA 1572_v3.0.pdf

Requirement * Form FDA 1572

File * [Change](#) Form FDA 1572_v4.0.pdf

Document Name * Form FDA 1572_v4.0.pdf

Effective Date 01 Jan 1900

Valid Until

Comments

Signature Requirement * ☒ Electronic Signature
☐ Wet Signature
☐ None

Signers Kacey Richards

Signature Meaning * Approved

Signature Placement [Choose Location](#) Default location

Due Date

Notes to Signers

Notify Now ☐ Yes ☒ No

[Create](#) [Cancel](#)

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.



Form FDA 1572_v5.0.pdf

Q

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▼

2

of 2

✕ Cancel Placement

STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.

2. Provide curriculum vitae or other statement of qualifications as described in Section 2.

3. Provide protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

1

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right.

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 person is not required to respond to, a collection of information unless it displays a currently 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 2 of 2

Save Location

Back

Form FDA 1572_v5.0.pdf

Q

^

▼

2

of 2

✎ Place Signature

STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.

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3. Provide protocol outline as described in Section 8.

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10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

Kacey Richards (klr4) Approved in Advarra eRegulatory on DD Mon YYYY HH:MM:SS -05:00 GMT

2

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

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FORM FDA 1572 (3/19)

PREVIOUS EDITION IS OBSOLETE.

Page 2 of 2

Save Location

Back

V5.0

22-Oct-2024

Page 8 of 12

Yale Center for

Clinical Investigation

Form FDA 1572_v5.0.pdf

2 of 2

Place Signature

3

1. Complete all sections. Provide a separate page if additional space is needed.

2. Provide curriculum vitae or other statement of qualifications as described in Section 2.

3. Provide protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

X

Kacey Richards (k1r4) Approved in Advarra eRegulatory on DD Mon YYYY HH:MM:SS -05:00 GMT

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Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

FORM FDA 1572 (3/19) PREVIOUS EDITION IS OBSOLETE. Page 2 of 2

Save Location Back

Form FDA 1572_v5.0.pdf

2 of 2

Place Signature

Date Format MM/DD/YYYY

3

1. Complete all sections. Provide a separate page if additional space is needed.

2. Provide curriculum vitae or other statement of qualifications as described in Section 2.

3. Provide protocol outline as described in Section 8.

4. Sign and date below.

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

X

MM/DD/YYYY

Kacey Richards (k1r4) Approved in Advarra eRegulatory on DD Mon YYYY HH:MM:SS -05:00 GMT

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Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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FORM FDA 1572 (3/19) PREVIOUS EDITION IS OBSOLETE. Page 2 of 2

4 Save Location Back



The location of a placed signature can be adjusted on a protocol document before 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 > YSM-GENERAL > Regulatory Documents > Form FDA 1572

Form FDA 1572 for YSM-GENERAL

Versions1

+ New Version

Form FDA 1572_v5.0.pdf

Actions

Details

Electronic Signature Routing

FileForm FDA 1572_v5.0.pdf

Effective Date01 Jan 1900

Valid Until

Comments

Signature RequirementElectronic Signature

Related Documents (0)

2

Electronic Signature Needed

Kacey Richards needs to electronically sign (placed signature)

Electronically Signed

No users have electronically signed this document.

3

Electronic Signature Details

Signer * Kacey Richards

Signature Meaning * Approved

Signature Placement * Choose LocationCustom location

Due Date

Notes to Signer

Notify Now * YesNo

4

Save

Cancel

Send Copy

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, 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:

Test

Erica Rocco ▾

User Profile

Signed Documents

Help


About

Queued Tasks

Logout

Delegated Tasks

Document Name ↑	Protocol Number ↑	Routed By	Signature Meaning	Signed Date ↑
Delegated Tasks - Clinical Research Assistant		Erica Rocco	Approved	29 Aug 2024
Delegated Tasks - Research Laboratory		Erica Rocco	Approved	29 Aug 2024
Protocol Delegated Tasks	1112009483	Erica Rocco	Approved	19 Jan 2022

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.

Protocols > YSM-GENERAL > Staff Training > Protocol Training

Protocol_v6.0_2024.01.09.pdf

Actions ▾

Details

File

Protocol_v6.0_2024.01.09.pdf

Effective Date

09 Jan 2024

Valid Until

15 Mar 2024

Comments

Signature Requirement

Electronic Signature

Related Documents (0) ▸

Add Related Document

Electronic Signature Routing

Add Signers

Electronic Signatures Needed

There are no electronic signatures still needed

Electronically Signed

View the signed document.

Jack Lance (tj43)

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:

Protocol.pdf **Document Name**

Details

Edit

File

[Protocol_v7.0_2024.03.15.pdf](#)

Effective Date

15 Mar 2024

Valid Until

Comments

Signature Requirement

Electronic Signature

Document Details

Requirement • Protocol Training

File • Change Protocol_v7.0_2024.03.15.pdf

Document Name • Protocol, v7.0_Aproved 2024.03.15.pdf

Effective Date • 15 Mar 2024

Valid Until

Comments

Signature Requirement • ☒ Electronic Signature
☐ Wet Signature
☐ None

Save

Cancel

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

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/>

