



eReg Guidance Document Staff Training Protocol Section

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Acronyms

CAPA: Corrective and Preventative Action Plan

EDC: Electronic Data Capture

IRB: Institutional Review Board

ISF: Investigator Site File

Uploading Documents to the Staff Training Section

The Staff Training protocol section is used exclusively for uploading training materials and routing the materials to relevant study staff for review. Each training material is filed in the Staff Training section, in addition to the appropriate section in the eReg template. For example, the approved protocol is filed in both the Protocol section and in the Staff Training section. The training material is routed for signature from the Staff Training section, with a signature meaning of “Read and Understood”, in order to document training on that document.

Examples of documents to route for training documentation include but are not limited to:

- Electronic Data Capture (EDC) Training Slide Deck
- EDC Training Video Script
- Institutional Review Board (IRB)-approved Protocol*
- Corrective and Preventative Action Plan (CAPA)
- Other protocol specific or system training materials

*When uploading an IRB-approved protocol, enter the effective date as the IRB-approval date.

When a new version of a training material is available, it is to be uploaded by layering onto the prior version. Enter a Valid Until date for the prior version equal to the Effective Date of the current version. Be sure to use consistent, standard naming conventions and follow version control guidelines.

When uploading a document that has been wet-signed, the Signature Date(s) must be entered for the training date(s) to appear in the Staff Training Trackers (Reports).

If multiple materials are relevant to one training attestation (ex. IRB-approved protocol and associated training slide deck) and you wish to route them together, the documents must be combined into a single PDF prior to uploading to the Staff Training section. Zipped files cannot be routed for signature within eReg. You may upload additional relevant training materials with the main file, such as corresponding training slides, using the “Add Related Document” button. Related documents can be routed with the main document for review, but electronic signature(s) will only be applied to the main document. Related documents do not appear in the Staff Training Trackers, and the recipient is not required by the system to open the related document(s) to sign-off on the main document.

Note that only one signature requirement method can be selected per document. I.e., for a document uploaded, either wet-ink signatures can be entered OR electronic signatures can be requested through the system, not a combination of both.





Documenting Staff Training Using Electronic Signatures

Only one signature requirement method can be selected per training document uploaded. It is advised to document Staff Training by requesting electronic signatures in eReg rather than collecting wet-ink signatures. This allows for clear, organized, and often more timely and compliant training documentation. A staff member documents training by reviewing the material(s) and providing electronic signature. 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.

1 Signature Requirement * Electronic Signature
 Wet Signature
 None

2 Signers

3 Signature Meaning

4 Signature Placement ⓘ Default location

5 Due Date

6 Notes to Signers

7 Notify Now ⓘ *

- 1: Select Electronic Signature for a training document (PDF) to be routed for electronic signature within eReg.
- 2: Select required signer(s). The document can be assigned based on all active protocol staff, by staff role, or by specific protocol staff members.
- 3: Select a Signature Meaning of "Read and Understood" for training documentation.
- 4: Training documents typically require multiple signers, so the signature placement must stay as Default location.
- 5: Select a due date (optional).
- 6: Enter a note directed to the signer(s) (optional).
- 7: It is recommended to select "Yes – Notify Now" so the signers are 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.

See the eReg Guidance Document – Electronic Signatures for additional details.





Documenting Staff Training Using Wet Signatures

While electronic signature on Staff Training materials is recommended, wet-ink signatures can be documented in eReg. When uploading a document that has been wet-signed, the Signature Date(s) must be entered for the training date(s) to appear in the Staff Training Trackers.

If collecting a Training Log and/or individual Training Attestations, add these signed documents as Related Documents. It is recommended that the “main” document be the training material.

1 Signature Requirement * Electronic Signature
 Wet Signature
 None

2 Signers

3 Signature Date

1: Select Wet Signature for a training document if the document has been signed outside of eReg, or if you are appending wet-ink signed Training Log/Attestations as Related Documents to the training material.

2: Add the Staff member(s) who documented training on the uploaded document by signing the document in wet-ink or by signing a training log/attestation in wet-ink.

3: Date of the wet signature(s). One date can be captured in this “Create Document” screen. Once the document is created, additional signers with different signature dates can be added.

Versions

+ New Version ▾

Protocol_v7.0_2024.03.15.pdf Actions ▾

Details Edit Wet Signatures Add Signers

File	Protocol_v7.0_2024.03.15.pdf	Wet Signed by Erica Rocco (erica.rocco@yale.edu) on 01 Jul 2024 ✕
Effective Date	15 Mar 2024	Add signed, scanned Training Logs and/or Attestations supporting the list of Wet Signatures.
Valid Until		
Comments		
Signature Requirement	Wet Signature	Add each staff member who signed the Log/Attestation and the date they signed.

Related Documents (1) ▾ Add Related Document Sent Copies (0) ▶ Send Copy

Training Attestation - Rocco, E_2024.07.01.pdf ✕
01 Jul 2024





Reports: Staff Training Trackers

Staff Training Tracker by Protocol

Research teams are encouraged to use the Staff Training Tracker by Protocol report to track training completion at the protocol level. The report includes a row for each staff member and a column for each staff training document version (see sample below).

Staff Training Tracker by Protocol						
Protocol: YSM-GENERAL - Yale University						
PIs: Kacey Richards						
First Name	Last Name	Staff Role	Start Date	Stop Date	Protocol_v1.0_2021.05.12.pdf 12 May 2021 - 12 Sep 2021	Protocol_v2.0_2021.09.12.pdf 12 Sep 2021 - Current
Kacey	Richards	Principal Investigator	03 Sep 2021		01 Jun 2021	16 Dec 2021
Erica	Rocco	Clinical Research Assistant	03 Sep 2021		01 Jun 2021	

For each staff training document, the active dates for that document are listed.

Staff Training Tracker by Staff Member

Research teams are encouraged to use the Staff Training Tracker by Staff Member report to track training completion for one or more staff members across protocols. The report includes a row for each staff training document associated with the selected staff member(s) (see sample below).

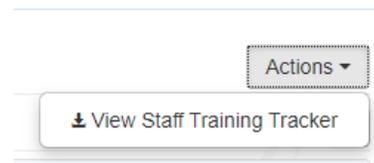
Staff Training Tracker by Staff Member											
Staff Members: Ann L. Kurtis, Ben R. Jones											
Include Signed Documents: Yes											
First Name	Last Name	Protocol	Study Site	Staff Role	Staff Start Date	Staff Stop Date	Staff Training Document Name	Document Effective Date	Document Valid Until Date	Signature Date	
Ann	Kurtis	ALK_107921	Multi-Site	Principal Investigator	18 Mar 2020	31 Dec 2020	Training Manual.pdf	19 Mar 2020		01 Apr 2020	
Ann	Kurtis	ALK_107921	Multi-Site	Principal Investigator	18 Mar 2020	31 Dec 2020	Protocol Training v3.pdf	19 Mar 2020	29 Apr 2020	01 Apr 2020	
Ann	Kurtis	PTL_20200304	East Clinic	Principal Investigator	04 Mar 2020		Clinical Practices.pdf	13 Mar 2020			
Ann	Kurtis	PTL_20200304	East Clinic	Principal Investigator	04 Mar 2020		Training Materials.pdf	13 Mar 2020		29 Apr 2020	
Ben	Jones	AAA Demo Protocol	Baylor - East Clinic	Affiliate Principal Investigator	01 Apr 2020		Training Manual.pdf	01 Apr 2020			
Ben	Jones	PTL_20200304	East Clinic	Affiliate Principal Investigator	29 Apr 2020		Training Materials.pdf	13 Mar 2020		29 Apr 2020	
Ben	Jones	PTL_20200304	East Clinic	Affiliate Principal Investigator	29 Apr 2020		Training Materials.pdf	13 Mar 2020			

Both Staff Training Tracker by Protocol and Staff Training Tracker by Staff Member are available to run from the Reports section of eReg:

Name ↑	Description
Staff Training Tracker by Protocol	Displays the signature status for a specified protocol's staff training documents. If this report is run for a multi-site protocol, only documents from the coordinating center are included.
Staff Training Tracker by Staff Member	Displays the signature status of staff training documents across protocols for specified staff.

2 Total Records

The Staff Training Tracker by Protocol can also be downloaded directly from the Staff Training section of the Investigator Site File (ISF), under the Actions button in the top-right corner.





Please review the eReg Learning Portal for additional report details and instructions on how to run reports.

Note: A blank cell in the report indicates that either the staff member has not completed required training, or the training is not applicable for the staff member. For example, if Protocol v2.0 is the current version when a new staff member joins the team, training documentation for Protocol v1.0 would not be required. The staff member will have a signature date for Protocol v2.0 only, while Protocol v1.0 remains blank.

Additional Resources

- eReg Guidance Document – Electronic Signatures
- eReg Guidance Document – Regulatory Templates
- eReg Learning Portal
- YCCI eReg website: <https://medicine.yale.edu/ycci/researchservices/systems/ereg/>

