

eReg Guidance Document

Delegation of Authority

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Acronyms

CRF: Case Report Form

DoA: Delegation of Authority

ECG: Electrocardiogram

eCRF: Electronic Case Report Form

FAQs: Frequently Asked Questions

IRB: Institutional Review Board

ISF: Investigator Site File

IVRS: Interactive Voice Response System

IWRS: Interactive Web Response System

PI: Principal Investigator

YCCI: Yale Center for Clinical Investigation

Overview of the Electronic Delegation of Authority Log in eReg

Delegation of Authority Log Definition and Use

The Delegation of Authority (DoA) log allows study-specific tasks to be delegated to staff members by the Principal Investigator (PI). It is a comprehensive list of study team members which is established at the start of a study and maintained throughout the lifecycle of the study until study closure. Each staff member and the PI sign off on their delegated tasks before the staff member performs any work on the study.

The Investigator Site File (ISF) templates built in eReg contain the fully electronic Delegation of Authority section and a section/requirement for Delegation of Authority (Paper). The study team may opt to maintain the DoA log in paper (wet ink) by scanning and uploading a new version of the document each time there is a change made. However, it is strongly recommended that study teams leverage the fully electronic DoA tool built into the eReg ISF to facilitate timely and compliant documentation.

The regulatory designee setting up the eReg ISF must remove the DoA section that is not being used.

Master Delegation of Authority Log

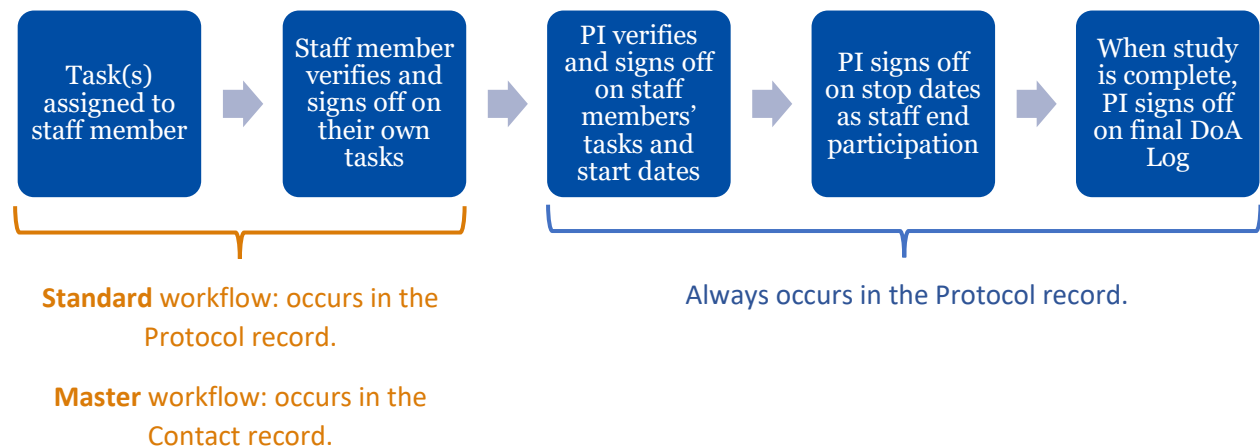
A Master Delegation of Authority (Master DoA) Log allows Staff Roles and associated Tasks to be assigned to staff members on a central log (often paper log) that is not protocol-specific. Typically, the Master DoA Log documents all staff, roles, and associated tasks for an entire research team or department. Each staff member approves and signs their role and assigned tasks on this central “Master” log.

When a staff member is added to a protocol-specific DoA Log with a role and tasks that they have already approved on the Master DoA Log, the Protocol DoA Log inherits the approved tasks and the individual does not need to sign again if no changes are needed. The Principal Investigator (PI) always



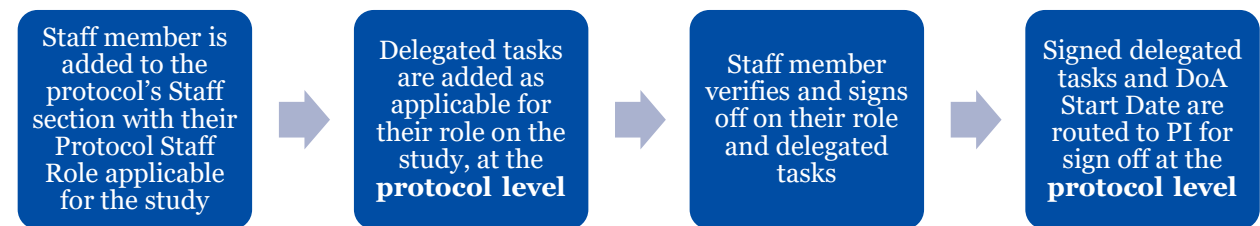
needs to approve and sign the protocol-specific DoA Log entry before the staff member performs any work on the study.

This guidance document describes electronic (not wet ink) delegation of authority in the eReg system. This document includes information on both the standard Delegation of Authority workflow and the Master Delegation of Authority workflow.



Standard Delegation of Authority Workflow in eReg

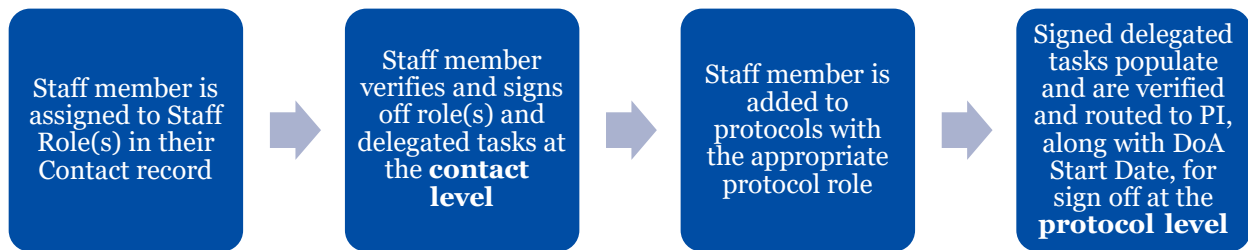
To use the standard electronic DoA workflow in eReg, a staff member is assigned a role and tasks in a protocol record. The tasks are electronically signed by the staff member within the protocol record. See section “Standard DoA Workflow: Delegated Tasks Added at the Protocol-Level” for details on using this approach.



Master Delegation of Authority Workflow in eReg

The eReg system supports a Master DoA workflow, which does not rely on a paper Master DoA Log. **This workflow leverages the eReg tool “Delegated Tasks by Staff Role” in a user’s Contact record.**

To use the master electronic DoA workflow in eReg, a staff member is assigned a role(s) and associated tasks in their Contact record > Delegated Tasks by Staff Role. The role(s) and tasks are electronically signed by the staff member one time. The signed tasks are then inherited by any protocol to which the staff member is added with a protocol role that matches one they signed at the contact level. The staff member does not need to re-sign in the protocol record if no changes are needed. See section “Master DoA Workflow: Delegated Tasks Added at the Contact-Level” below for details on using this approach.



Note: Both the Standard Delegation of Authority workflow and the Master Delegation of Authority workflow can be used to build a protocol-specific DoA Log in eReg. It is possible to use both approaches in a single protocol DoA, as needed.

After the staff member signs off on their tasks, regardless of which DoA workflow is used, the tasks and protocol-specific DoA start date must be routed to the PI for electronic signature in the protocol record. When a staff member ends their participation in the study or changes roles on the study, their protocol-specific DoA stop date is routed to the PI for electronic signature as well. When the study is complete and ready for closure with the Institutional Review Board (IRB), the completed DoA is electronically signed-off by the PI, which produces the final Delegation of Authority Report. **The signature meaning “Approved” is used for all electronic signatures related to the DoA.**

Information on the Electronic Delegation of Authority Log

When a protocol is imported from OnCore into eReg, most of the protocol details are imported along with it. Sponsor, Department(s), Study Site, and any unique Identifiers are manually added after import, before the DoA is set up. Refer to Yale Center for Clinical Investigation (YCCI) eReg website and the *eReg Protocol Import/Creation Guide* for information about eReg Protocol import/creation.

Ensure that the following details are complete and correct in your ISF, as they are included on the Delegation of Authority log report:

- Principal Investigator
- Sponsor
- Protocol Number
- IRB Protocol Number
- Protocol Title

Study staff members are added to the eReg ISF by a Yale Regulatory Coordinator, Yale Regulatory Manager and/ or PI. All staff members listed in the staff section of the ISF are, by default, included on the Delegation of Authority log. It is possible to remove staff from the Delegation of Authority log if their DoA entry has not yet been signed by the PI. See “Removing Staff” section below.

Delegated Tasks

There are two options for setting up and maintaining a Delegation of Authority log in eReg: Standard Delegation of Authority workflow and Master Delegation of Authority workflow. Consider the two options to determine the best approach for the research team and the team’s portfolio of studies. It is



possible to use both approaches in a single protocol DoA, as needed. Table 1 includes a list of Delegated Tasks by Staff Role in eReg. Table 2 includes the list of Delegated Tasks available in eReg.

Standard DoA Workflow: Delegated Tasks Added at the Protocol-Level

Delegated tasks can be individually added to a staff member at the protocol level. The tasks that can be individually added are selected from a reference list in eReg (see Table 2). **These tasks are only applied to the specific protocol and are not automatically inherited by other protocols to which the staff member is assigned.** When using the standard DoA workflow, delegated tasks are assigned to each staff member who is not using role-defined tasks (Master DoA approach). The delegated tasks must be signed by the staff member prior to routing to the PI for review and sign off.

Adding Tasks in a Protocol Record

To add delegated tasks at the protocol level, (1) navigate to the Protocol Staff page within the protocol record. (2) Select the staff member whose delegated tasks you would like to update.

Protocols > YSM-GENERAL > Staff

Select Protocol

Overview

Document Inbox

Summary

Details

Organizations

Staff

Consent Documents and HIPAA Authorization Forms

Delegation of Authority

Delegation of Authority (Paper)

Investigational Product

Protocol: YSM-GENERAL

Staff

	First Name ↑	Last Name ↑	Start Date	Stop Date
	Stephanie	Brogan	03 Sep 2021	
	Kacey	Richards	03 Sep 2021	
	Erica	Rocco	03 Sep 2021	

3 Total Records

(3) Review the delegated tasks assigned to that staff member and (4) select Add Delegated Tasks in the actions drop down menu.

Protocols > YSM-GENERAL > Staff > Erica Rocco > Delegated Tasks

Select staff

Summary

Details

Credentials

Protocol Staff Roles

Delegated Tasks

Routed Staff Training Documents

Routed Protocol Documents

Access Roles

Staff: Erica Rocco

Delegated Tasks

Signature Status Not Routed for Electronic Signature

Delegated Task ↑		
Conduct informed consent		
Determine subject eligibility	5	✕ Delete
Evaluate study assessments	4	✕ Delete

+

Add Delegated Tasks

↓

View Delegated Tasks

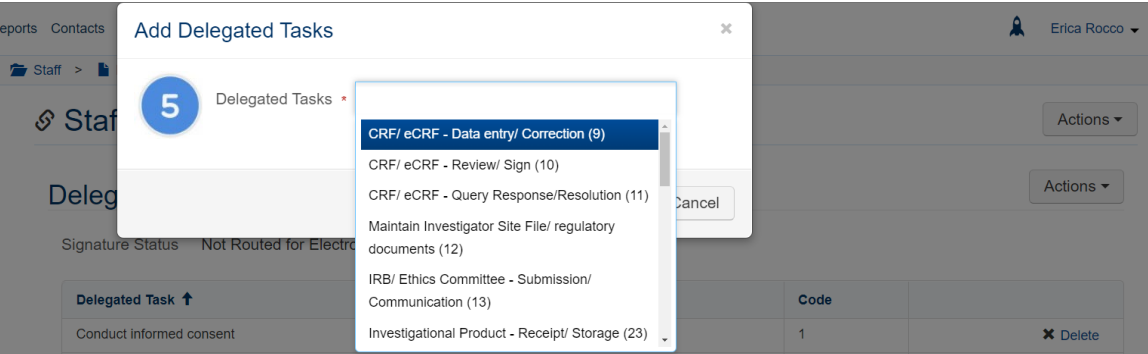
→

Route Delegated Tasks

✕

Remove Staff from Delegation of Authority Log

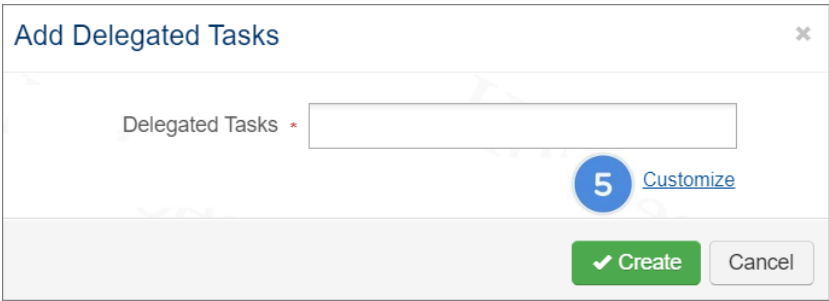
(5) Select all applicable delegated tasks from the reference list and then route delegated tasks for electronic signature using the signature meaning “Approved” (see “Routing Delegated Tasks for Study Staff Signoff at the Protocol Level” section below).



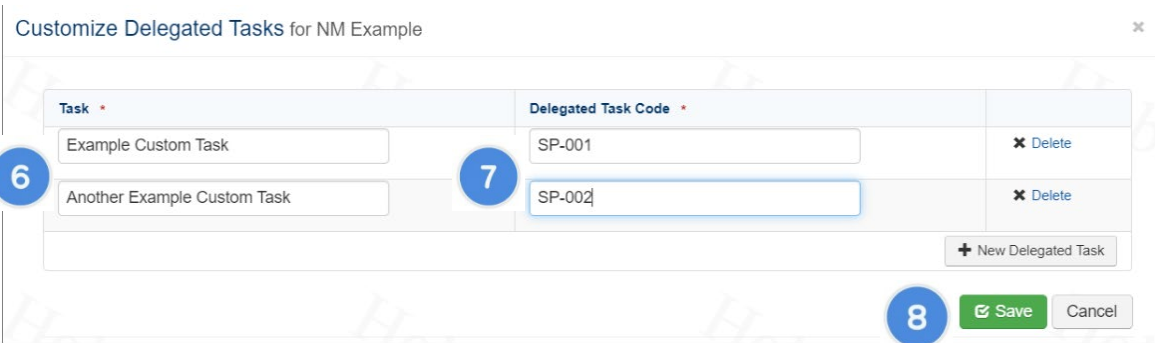
Custom Delegated Tasks

If a protocol calls for a very specific task that is not available within the reference list in eReg (Table 2), this task can be created at the protocol level. System Administrators, Yale Regulatory Coordinators, Yale Regulatory Managers, and Multi-Site user roles can create custom tasks at the protocol level. We recommend reserving this option for discrete tasks that are very study-specific and otherwise using tasks available within the reference list. Contact eReg.Support@yale.edu if you believe a custom task should be added to the reference list for more widespread use.

Follow instructions 1 – 4 above in the Adding Tasks in a Protocol Record section for adding delegated tasks individually. After step (4) selecting Add Delegated Tasks from the actions drop down menu, select Customize (5).



(6) Add the task in the Task free-text field and (7) add the Delegated Task Code in the free-text field. (8) Save your entry(-ies).



Routing Delegated Tasks for Study Staff Signoff at the Protocol Level

(1) Verify all applicable tasks are appropriately delegated then (2) select Route Delegated Tasks from the action drop down menu.

Protocols

>

YSM-GENERAL

>

Staff

>

Erica Rocco

>

Delegated Tasks

Select staff

Summary

Details

Credentials

Protocol Staff Roles

Delegated Tasks

Routed Staff Training Documents

Routed Protocol Documents

Access Roles

Staff: Erica Rocco

Actions

Delegated Tasks

Signature Status

Not Routed for Electronic Signature

Delegated Task

Conduct informed consent

CRF/ eCRF - Data entry/ Correction

Determine subject eligibility

9

5

Delete

Delete

+

Add Delegated Tasks

+

View Delegated Tasks

+

Route Delegated Tasks

+

Remove Staff from Delegation of Authority Log

(3) Route delegated tasks for electronic signature using the signature meaning “Approved”. Add a due date or notes to signer (optional).

Route Delegated Tasks

Delegated Tasks

Conduct informed consent (1)

CRF/ eCRF - Data entry/ Correction (9)

Determine subject eligibility (5)

Evaluate study assessments (4)

Investigational Product - Prescribe (22)

Perform physical exams (2)

Perform study assessments (3)

Safety Event - Assess causality, attribution and severity (7)

Safety Event - Collect Data (6)

Safety Event - Report (8)

Subject recruitment (18)

Signature Meaning

Approved

Due Date

Notes to Signer

Notify Now

Yes

No

Route

Cancel

Master DoA Workflow: Delegated Tasks Added at the Contact-Level

The Master Delegation of Authority workflow is oftentimes the most efficient approach for maintaining the Delegation of Authority log in eReg. This approach is best suited for study staff in low variability roles (i.e., principal investigators, sub-investigators, pharmacists, pharmacy technicians, regulatory coordinators, etc.). For roles with high variability (i.e., clinical research coordinators, research nurses, etc.), it may be preferable to add delegated tasks individually for specific protocols.

The following protocol staff roles have been configured with a default set of delegated tasks to facilitate use of the Master DoA workflow (Table 1).

- Clinical Research Assistant

- Clinical Research Coordinator
- Data Manager
- Pharmacist
- Pharmacy Technician
- Principal Investigator
- Regulatory Coordinator / Regulatory Manager
- Research Laboratory
- Research Nurse
- Sub-Investigator

These staff roles can be added at the contact level without any changes to the default delegated tasks needed and then routed to the staff member for verification and signature. A signature meaning of “Approved” is used.

An individual can have more than one staff role on their contact record; however, only one staff role can be assigned per protocol. For example, an investigator who serves as PI and Sub-Investigator on studies within the investigator’s department will have a staff role of Principal Investigator and Sub-Investigator assigned to their contact record. However, when that investigator serves as the PI for a specific study, only the staff role of Principal Investigator will be applied to the protocol record and the tasks signed off for the PI role will be inherited for that protocol.

After a staff role is routed for signature at the contact level, the staff member will sign off on each staff role one time. The delegated tasks associated with the staff role are then inherited by every protocol to which the staff member is added using that role moving forward.

Setting up Delegated Tasks by Staff Role for Yourself or a Member of Your Study Team

View the individual’s Delegated Tasks by Staff Role by (1) navigating to their contact record: Admin > Contacts > select the user.

Menu

Admin

Protocols

Regulatory Templates

Reports

SOPs

Sign Documents

Review Sessions

INDs

Test

Kacey Richards

Contacts

Contacts

Search

kacey

Choose Columns

Export

New Contact

Home Organization

Active Contact

Yes

No

First Name	Last Name	Home Organization	Active Contact	Active User Account	Username
Kacey	Richards	Yale Center for Clinical Investigation	Yes	Yes	klr4

1 Total Record

Select Delegated Tasks by Staff Role (2) in the left pane.

Menu

Protocols

Contacts

Organizations

Review Sessions

Reports

Regulatory Templates

Reference Lists

Test

Erica Rocco

Contacts > Kacey Richards > Delegated Tasks by Staff Role

Select contact

Summary

Details

User Account Details

Credentials

Delegated Tasks by Staff Role

Contact: Kacey Richards

Actions

Delegated Tasks by Staff Role

Add Delegated Tasks by Staff Role

Protocol Staff Role	Delegated Tasks	Signature Status	
Clinical Research Assistant	Safety Event - Report (8), CRF/ eCRF - Data entry/ Correction (9), CRF/ eCRF - Query Response/Resolution (11) and 2 more	Needs Electronic Signature	Edit Delete

Click the Add Delegated Tasks by Staff Role (3) button.

eREG

Menu
Admin
Protocols
Regulatory Templates
Reports
SOPs
Sign Documents
Review Sessions
INDs

Test
Kacey Richards

Contacts

Kacey Richards

Delegated Tasks by Staff Role

Select contact

Contact: Kacey Richards

Actions

Summary

Details

User Account Details

Credentials

Delegated Tasks by Staff Role

3

+ Add Delegated Tasks by Staff Role

Protocol Staff Role

Delegated Tasks

Signature Status

In the pop-up window (4), complete all fields.

[A] Protocol Staff Role – Select the Protocol Staff Role you are wanting to configure for this user.

Note- More than one Protocol Staff Role can be configured for a user, if they fill different protocol roles across their studies. Each Protocol Staff Role that is configured will have its own associated tasks.

[B] Delegated Tasks – If you select one of the pre-configured Protocol Staff Roles listed above, the set of delegated tasks will automatically populate. The list of default tasks can be adjusted for the user, if needed.

If you select a Protocol Staff Role that has not been pre-configured with tasks, no tasks will automatically populate, and you will select each task individually from the drop-down.

[C] Signature Requirement – Select **Electronic Signature** and complete the additional fields. You will select a Signature Meaning of **Approved** from the dropdown.

The user **must** electronically sign off on their Delegated Tasks by Staff Role in the eReg system in order to leverage the Master DOA workflow and have the signed tasks flow into all future protocols they are added to with the signed Protocol Staff Role.

4

Add Delegated Tasks by Staff Role

A

Protocol Staff Role *

Clinical Research Assistant

B

Delegated Tasks

Safety Event - Report (8)

CRF/ eCRF - Data entry/ Correction (9)

CRF/ eCRF - Query Response/Resolution (11)

Research Biospecimens - Process (30)

Research Biospecimens - Ship (31)

Signature Requirement *

Electronic Signature

None

Signature Meaning *

Approved

Due Date

Notes to Signer

Notify Now *


Yes

No

Create

Cancel

V4.0
30-Sep-2024
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Yale Center for
Clinical Investigation



Start and Stop Dates

Adding Start Dates

A Protocol Staff Start Date must be entered when adding a staff member to a protocol in eReg. This date indicates when the individual can sign documents for the protocol and access the protocol record (if their user permissions allow). The 'Protocol Staff Start Date' automatically populates the 'Delegation of Authority Start Date'; however, these dates are defined differently and the DoA Start Date should be corrected before PI sign-off.

Protocol Staff Start Date: The date the staff member has access to begin viewing and updating the protocol record, and/ or to begin signing documents within the eReg system for that protocol.

- Note: Protocol-required contact credentials must cover the period from Protocol Staff Start Date to Protocol Staff Stop Date (or to today's date if no stop date is entered yet). If there is a gap in a credential at any point during that duration, the Credential Status will show as 'Incomplete'.

Delegation of Authority (DoA) Start Date: The date the staff member can start participating in the study, as defined by the department. Consider a staff member's IRB approval status, if applicable, protocol training status and the overall protocol status (i.e., in study start-up vs. open to enrollment) when determining DoA start dates.

By default, the Delegation of Authority Start Date is set to the same date as the Protocol Staff Start Date. If the Protocol Staff Start Date value is changed, that update flows into the DoA Start Date if the PI has not yet signed the DoA entry. **The DoA Start Date will often be a different date than the Protocol Staff Start Date; therefore, you must change the DoA Start Date prior to routing for PI sign off.**

The Delegation of Authority Start Date cannot be changed after the DoA entry has been signed by the Principal Investigator. Ensure the start date is correct before routing staff entries to the PI for electronic signature. See "Delegation of Authority Log Corrections" section below for more information on how to correct errors in the DoA.

Routing Tasks and Start Dates for PI Signoff

Routing a DoA entry for PI sign off is the same process, regardless of if you are using the standard or master DoA workflow.

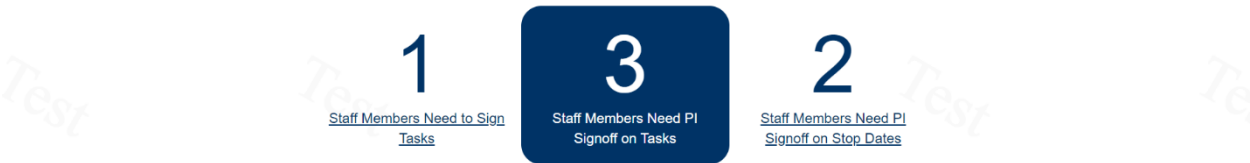
(1) Confirm Delegated Tasks and DoA Start Date are correct prior to routing to the PI. To route study member tasks and start dates to the PI, (2) select the "Route to PI for electronic signature" checkbox. This action is called PI Sign Off on Tasks in eReg and is a sign off of tasks and the start date.

Then (3) click Route Selected. Note that once routed for PI signoff, the staff member's Delegation of Authority start date, role, and task(s) are read-only unless the routing is undone.



Delegation of Authority

Actions



Staff Members Need PI Signoff on Tasks

Principal Investigator Kacey Richards

Select All | None

Route Selected

Jack Lance

Details

Protocol Staff Roles

Clinical Research Coordinator

Protocol Staff Start Date

03 May 2023

Delegation of Authority Start Date

01 May 2023

Delegated Tasks

Conduct informed consent (1)

Perform study assessments (3)

Determine subject eligibility (5) and 8 more

CONFIRM

Go to Protocol Staff

Electronic Signature Routing

Tasks Electronically Signed by Staff

Jack Lance (tj43) Approved on 05 Dec 2022

Tasks Electronically Signed by PI

Needs Routing for Electronic Signature

Route to PI for electronic signature

The PI will review and sign delegated tasks and start dates via the Sign Documents page similar to any other signature collected within eReg.

eREG

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Refer to the Learning Portal for more information on how to route tasks and start dates for PI signoff.

Adding Stop Dates

Staff members must be given a stop date on the DoA equal to the date their work on the protocol is complete. This includes staff members who leave the University.



Similar to start dates, eReg includes two stop dates: 'Protocol Staff Stop Date' and 'Delegation of Authority Stop Date'. These dates function in the same manner as the start dates, except they terminate access to the protocol record and denote end of participation in the conduct of a study, respectively.

Protocol Staff Stop Date: The date the study staff member no longer needs access to the eReg record. Past, current and future dates can be selected. This date must be entered in order to add a Delegation of Authority Stop Date. A study staff member requires access to the eReg record in order to route stop dates for PI sign off, to route the DoA for final PI signoff and to lock the protocol. Consider who will be routing stop dates, final PI signoff and locking the protocol when adding protocol staff stop dates.

- Note: Protocol-required contact credentials must cover the period from Protocol Staff Start Date to Protocol Staff Stop Date. If there is a gap in a credential at any point during that duration, the Credential Status will show as 'Incomplete'.

Delegation of Authority Stop Date: The date the study staff member ends their participation in the study.

Date ranges in eReg are based on midnight. Start Dates go into effect at 12:00 AM on the specified date, while the date entered in the Stop Date field is when the staff member is no longer active on the protocol. For example:

- A staff member with a Stop Date of 13 Nov 2018 means that their last active day on the protocol was 12 Nov 2018.

By default, the Delegation of Authority Stop Date is set to the same date as the Protocol Staff Stop Date. The Delegation of Authority Stop Date can be removed from the Staff record > Delegated Tasks section (which also removes it from the DoA) if it has not yet been signed off by the PI. If the Protocol Staff Stop Date value is changed, that update flows into the DoA Stop Date if the PI has not yet signed the DoA Stop Date. **The DoA Stop Date may be a different date than the Protocol Staff Stop Date; therefore, you must confirm the Delegation of Authority Stop Date prior to routing for PI sign off.**

The Delegation of Authority Stop Date cannot be changed after the DoA Stop Date has been signed by the Principal Investigator. Ensure the stop date is correct before routing to the PI for electronic signature. See "Delegation of Authority Log Corrections" section below for more information on how to correct errors in the DoA.

Routing Stop Dates for PI Signoff

(1) Confirm DoA Stop Dates are correct prior to routing to the PI. To route study member stop dates to the PI, (2) select the "Route to PI for electronic signature" checkbox.

Then (3) click Route Selected. Note that after the Delegation of Authority stop date has been routed to the PI, it is view-only unless the routing is undone.



Staff Members Need PI Signoff on Stop Dates

Principal Investigator
Kacey Richards

Select All | None
Route Selected

Erica Rocco

Details

Edit

Electronic Signature Routing

Protocol Staff Roles

Regulatory Coordinator

Protocol Staff Stop Date

31 Dec 2021

Delegation of Authority Stop Date

10 Nov 2021

CONFIRM

Tasks Electronically Signed by Staff

Erica Rocco (erica.rocco@yale.edu) Read and Understood on 13 Sep 2021

Tasks Electronically Signed by PI

Kacey Richards (klr4) Read and Understood on 13 Sep 2021

Delegation of Authority Stop Date Electronically Signed by PI

Needs Routing for Electronic Signature

Go to Protocol Staff

2

Route to PI for electronic signature

3

Route Selected


The PI will review and sign stop dates via the Sign Documents page similar to any other signature collected within eReg.

Refer to the Learning Portal for more information on how to route stop dates for PI signoff.

Linked Staff Records

Prior to 18-Oct-2021, certain staff records were linked between OnCore and eReg. A linked icon appears next to study staff names for any staff records that are linked as shown below.

Staff

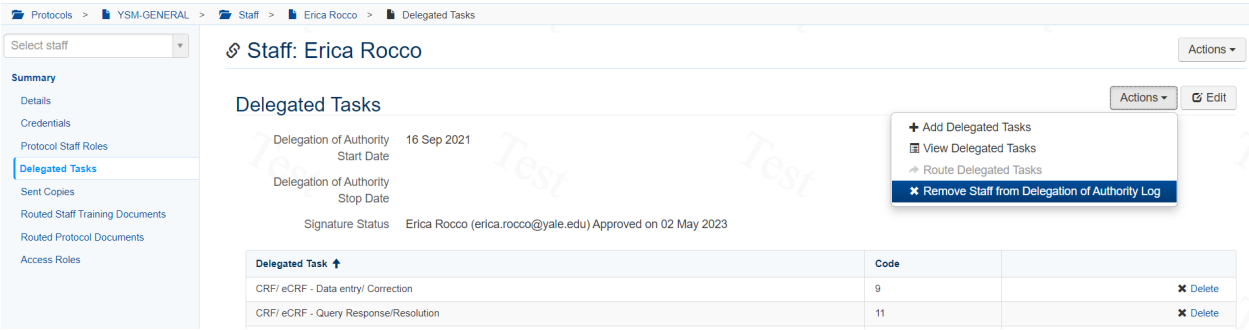
	First Name ↑
	Kacey

The Protocol Staff Start and Stop Date for linked staff must be entered in the OnCore PC Console > Main > Staff section. Dates entered in OnCore flow into eReg and appear on the Delegation of Authority log if the DoA entry has not yet been signed by the PI.

Effective 18-Oct-2021, protocol staff are no longer being imported from OnCore to eReg and the staff records are no longer linked. Updates to Protocol Staff Start and Stop Dates for unlinked staff records are made directly in eReg.


Removing Staff from the Delegation of Authority Log

It is possible to remove a staff member from the Delegation of Authority log if that staff member's DoA entry has not yet been routed to the PI for signature (you can un-route prior to PI signature). To remove the staff member from the DoA, select 'Remove Staff from Delegation of Authority Log' from the Actions button menu in the staff member's record for the protocol.



Delegation of Authority Log Corrections

Corrections to Staff Roles and/ or Delegated Tasks in the Contact Record





If the Delegated Tasks by Staff Role has not yet been signed by the staff member in their contact record, edits can be made by simply clicking the ‘ Edit’ button to make necessary changes.

To correct delegated tasks that have been signed by the staff member in their contact record, navigate to the user’s contact record > Delegated Tasks by Staff Role. (1) Delete the incorrect staff role, then (2) add the correct staff role and correct delegated tasks.

Delegated Tasks by Staff Role

+ Add Delegated Tasks by Staff Role

2

Protocol Staff Role	Delegated Tasks	Signature Status	
Clinical Research Assistant	Safety Event - Report (8), CRF/ eCRF - Data entry/ Correction (9), CRF/ eCRF - Query Response/Resolution (11) and 2 more	Needs Electronic Signature	 Edit  Delete
Clinical Research Coordinator	Perform study assessments (3), Determine subject eligibility (5), Safety Event - Collect Data (6) and 7 more	Electronically Signed	 Delete
Principal Investigator	Perform study assessments (3), Evaluate study assessments (4), Determine subject eligibility (5) and 6 more	Electronically Signed	 Delete

1

(3) Changes require re-routing for electronic signature within the eReg system, with the signature meaning of “Approved”.

Add Delegated Tasks by Staff Role

Protocol Staff Role

Clinical Research Coordinator

Delegated Tasks

Conduct informed consent (1)

CRF/eCRF - Data Entry/Correction (9)

CRF/eCRF - Query Response/Resolution (31)

Determine subject eligibility (5)

Perform study assessments (3)

Safety Event - Collect Data (6)

Safety Event - Report (8)

Signature Requirement

☒ Electronic Signature

☐ None

Signature Meaning

Approved

Due Date

Notes to Signer

Notify Now

☒ Yes ☐ No

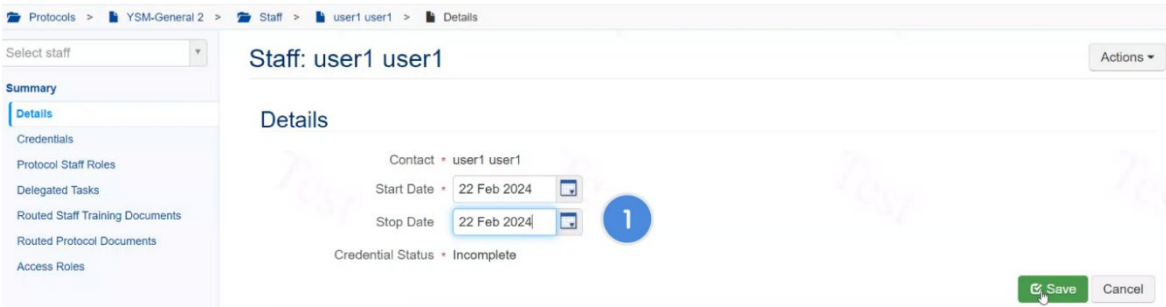
Create

Cancel

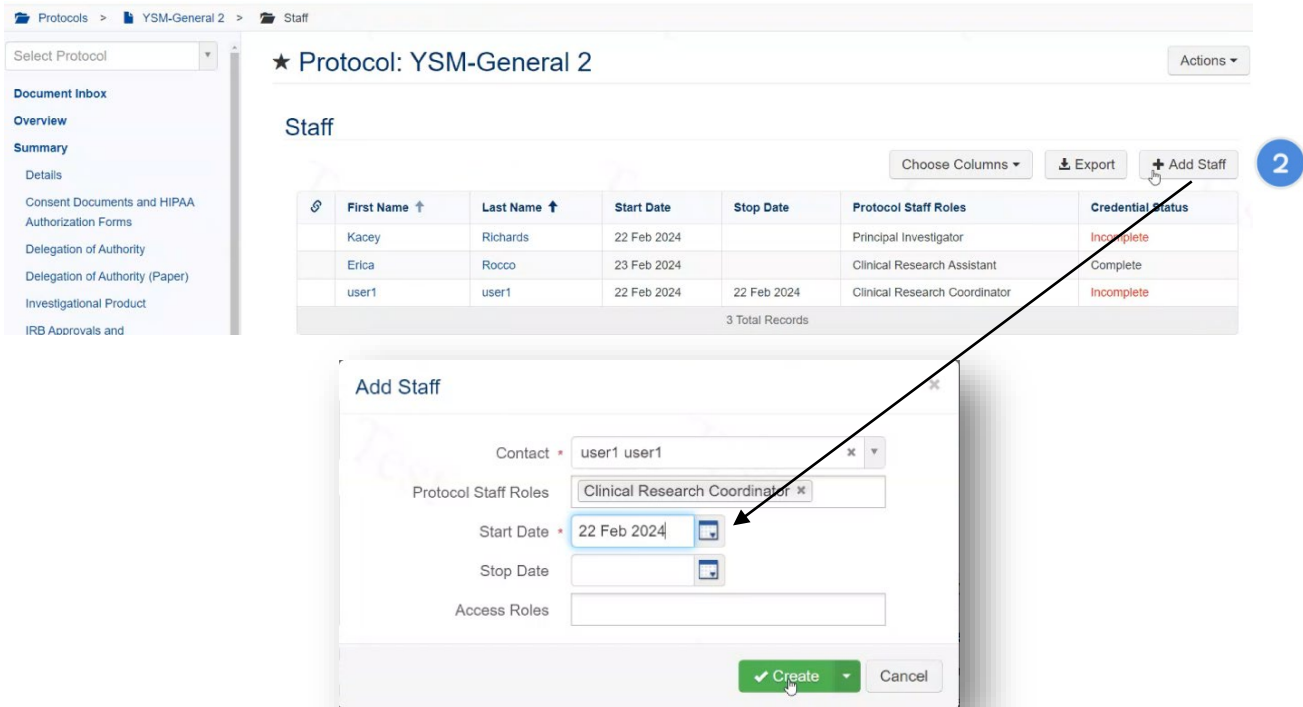
Once the individual signs off on their Staff Role and associated tasks, the signed tasks will appear in protocols they are added to moving forward (existing DoA entries will not change).

Corrections to Staff Roles, Delegated Tasks, Start Dates and/ or Stop Dates in the Protocol Record

To correct a staff role, delegated tasks, start dates, and/ or stop dates that have been signed by the PI for a staff member in a protocol record, (1) enter a Stop Date for the staff member in the Staff > Details section. It is recommended to use a stop date equal to the incorrect DoA entry’s start date, to indicate that the staff member did not participate in the study under the incorrect role/tasks. The stop date entered will also populate in the Delegation of Authority Stop Date field in the Delegated Tasks tab.



(2) Re-add the staff member in the Staff section with a Start Date equal to the Stop Date entered for the original entry or alternative appropriate date. Keep in mind that a study team member cannot have more than one active staff role delegated on a protocol at a time.



(3) Confirm the Role and Delegated Tasks are correct and approved by the staff member for the newly added entry.

Select Protocol

Document Inbox

Overview

Summary

Details

Consent Documents and HIPAA Authorization Forms

Delegation of Authority

Delegation of Authority (Paper)

Investigational Product

IRB Approvals and Acknowledgements

★ Protocol: YSM-General 2

Staff

Choose Columns ▾

Export

Add Staff

	First Name ↑	Last Name ↑	Start Date	Stop Date	Protocol Staff Roles	Credential Status
	Kacey	Richards	22 Feb 2024		Principal Investigator	Incomplete
	Erica	Rocco	23 Feb 2024		Clinical Research Assistant	Complete
	user1	user1	22 Feb 2024		Clinical Research Coordinator	Incomplete
	user1	user1	22 Feb 2024	22 Feb 2024	Clinical Research Coordinator	Incomplete

4 Total Records

Summary

Details

Credentials

Protocol Staff Roles

Delegated Tasks

Routed Staff Training Documents

Routed Protocol Documents

Access Roles

Delegated Tasks

Actions ▾

Edit

Delegation of Authority

Start Date

22 Feb 2024

CONFIRM

Delegation of Authority

Stop Date

Signature Status

user1 user1 (user1) Approved on 16 May 2019

Delegated Task ↑	Code	
Conduct informed consent	1	Delete
CRF/ eCRF - Data entry/ Correction	9	Delete
Determine subject eligibility	5	Delete
IVRS/IWRS entry	14	Delete
Perform study assessments	3	Delete

5 out of 7 (Go to List)

(4) Enter the correct Delegation of Authority Start Date and revise delegated tasks as needed in the Delegated Tasks tab of the newly added staff record. The start date can also be reviewed and edited as needed in the Delegation of Authority section of the protocol record, prior to PI sign off.

Staff section:

Summary

Details

Credentials

Protocol Staff Roles

Delegated Tasks

Routed Staff Training Documents

Routed Protocol Documents

Access Roles

Delegated Tasks

Delegation of Authority Start Date22 Feb 2024

Delegation of Authority Stop Date

Signature Statususer1 user1 (user1) Approved on 16 May 2019

Delegated Task ↑

Conduct informed consent	1	✕ Delete
CRF/ eCRF - Data entry/ Correction	9	✕ Delete
	5	✕ Delete
	14	✕ Delete
	3	✕ Delete

out of 7 (Go to List)

Actions ▾

Edit

4

+ Add Delegated Tasks

View Delegated Tasks

Route Delegated Tasks

Remove Staff from Delegation of Authority Log

Add Delegated Tasks

Delegated Tasks *

Customize

CreateCancel

Summary

Details

Credentials

Protocol Staff Roles

Delegated Tasks

Routed Staff Training Documents

Routed Protocol Documents

Access Roles

Delegated Tasks

Delegation of Authority *22 Feb 2024

Delegation of Authority Stop Date

Signature Statususer1 user1 (user1) Approved on 16 May 2019

Actions ▾

Delegation of Authority section:

user1 user1

Details

Protocol Staff RolesClinical Research Coordinator

Protocol Staff Start Date22 Feb 2024

Delegation of Authority Start Date22 Feb 2024

Delegated TasksConduct informed consent (1)
Perform study assessments (3)
Determine subject eligibility (5)
and 4 more

Go to Protocol Staff

4

Edit

Electronic Signature Routing

Tasks Electronically Signed by Staff
user1 user1 (user1) Approved on 16 May 2019

Tasks Electronically Signed by PI
Needs Routing for Electronic Signature

Edit Details for user1 user1

Protocol Staff RolesClinical Research Coordinator

Protocol Staff Start Date22 Feb 2024

Delegation of Authority *22 Feb 2024

Delegated TasksConduct informed consent (1)

(5) Route the corrected entry to the PI for electronic signature.

Staff Members Need PI Signoff on Tasks

Principal Investigator
Kacey Richards (I)

Select All | None
Route Selected

5

user1 user1

Details

Edit

Electronic Signature Routing

Tasks Electronically Signed by Staff

user1 user1 (user1) Approved on 16 May 2019

Tasks Electronically Signed by PI

Needs Routing for Electronic Signature

Go to Protocol Staff

☒ Route to PI for electronic signature

(6) Route the added/corrected stop date to the PI for electronic signature.
Note: PI must sign off on tasks and the start date before the stop date can be signed off.

Staff Members Need PI Signoff on Stop Dates

Principal Investigator
Kacey Richards

Select All | None
Route Selected

6

user1 user1

Details

Edit

Electronic Signature Routing

Tasks Electronically Signed by Staff

user1 user1 (user1) Approved on 16 May 2019

Tasks Electronically Signed by PI

Kacey Richards (klr4) Approved on 22 Feb 2024

Delegation of Authority Stop Date Electronically Signed by PI

Needs Routing for Electronic Signature

Go to Protocol Staff

☒ Route to PI for electronic signature

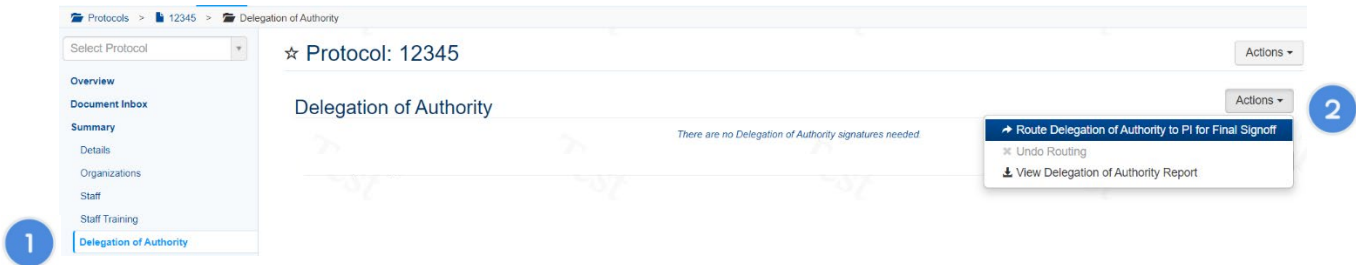
You can make changes to roles and tasks until they have been signed by the staff member. If they have been signed by the staff member, you will need to delete and reroute the role and tasks for electronic signature after you have edited the role and/ or tasks. You can make changes to the start and stop dates until they have been signed by the PI. If the start or stop dates have been signed by the PI, you will need to follow the steps above to correct the signed DoA entry.

Routing Delegation of Authority Report for Final PI Signoff

The Delegation of Authority report is routed to the PI for Final Signoff at the time of permanent study closure, oftentimes following a sponsor close out visit or equivalent. All staff members must have

Delegation of Authority Start and Delegation of Authority Stop Dates entered and signed off in order to route for final signoff by the PI.

To route to Delegation of Authority report for final PI signoff, (1) go to the Delegation of Authority section of the protocol and (2) choose ‘Route Delegation of Authority to PI for Final Signoff’ from the Actions button menu.



(3) Route for final PI signoff using the signature meaning “Approved”. Add a due date or notes to signer (optional).

The screenshot shows a modal dialog box titled 'Route Delegation of Authority to PI for Final Signoff'. At the top, there is an information icon and a message: 'After routing the Delegation of Authority to the PI, you can't make updates to the protocol staff list unless you undo this routing.' Below this, there are several input fields: 'Principal Investigator' with a dropdown menu showing 'Kacey Richards', 'Signature Meaning' with a dropdown menu showing 'Approved', 'Due Date' with a date picker icon, and 'Notes to Signer' with a text area. At the bottom left, there is a 'Notify Now' checkbox with 'Yes' and 'No' options. At the bottom right, there are two buttons: 'Route' (green) and 'Cancel' (grey). A blue circle with the number '3' is placed next to the 'Principal Investigator' field.

Note: if there are no active PIs to route this report to, you can choose from the inactive PIs (if there are more than one) or the system will include the inactive PI as the user to route to by default (if there is only one).

Once routed for PI final signoff, you can neither add staff members to the protocol nor update the protocol details included in the Delegation of Authority Report (Principal Investigator, Sponsor, Protocol Number, IRB Protocol Number, and Protocol Title) unless the routing is undone. Once the PI signs, no edits can be made.



FAQs

Master Delegation of Authority Log Workflow

1. What are the benefits of using the Master DoA workflow in eReg?

Using the eReg Master DoA functionality enhances efficiency and reduces administrative burden for study staff, who only need to sign off on their role(s) and tasks once, rather than each time they are added to a new protocol.

2. Who should use the Master DoA workflow in eReg?

Delegated Tasks by Staff Role can be configured for any eReg user in eReg; however, there are situations when the Master DoA workflow can be leveraged more than others. Utilizing the Master DoA workflow in eReg is most efficient for those staff members who perform a standard set of tasks across most of the protocols they participant in. If a staff member has high variability in the tasks they perform across protocols, the Master DoA workflow may not be appropriate.

3. What if I serve in different roles on different protocols? Can I still leverage the Master DOA workflow?

Yes. An individual can have more than one staff role on their contact record; however, only one staff role can be assigned per protocol. For example, an investigator who serves as PI and Sub-Investigator on studies within the investigator's department will have a staff role of Principal Investigator and Sub-Investigator assigned to their contact record. However, when that investigator serves as the PI for a specific study, only the staff role of Principal Investigator will be applied to the protocol record and the tasks signed off for the PI role will be inherited for that protocol.

4. What if my Protocol Staff Role has not been configured with tasks in eReg?

The Master DOA workflow can still be leveraged for users whose protocol staff role is different from those listed above. Use the "Delegated Tasks by Staff Role" tool in the user's contact card to add a staff role and associated tasks for signature at the contact level.

5. When using the Master Delegation of Authority workflow, do staff members who are assigned additional delegated tasks for a specific protocol need to re-sign off on tasks at the protocol level?

Yes. If additional or custom delegated tasks are added to a staff member after they have signed off on the Master delegated tasks, the staff member will need to sign their new list of tasks in the protocol record.

6. I set up Delegated Tasks by Staff Role for myself/a member of my team, but I do not see the tasks listed in the staff section of the protocol.

In order for a staff member's tasks to flow into the protocol, the Delegated Tasks by Staff Role must be set up for the contact BEFORE they are added to the protocol record.



7. I updated the Delegated Tasks by Staff Role for myself/ a member of my team, but the updates are not flowing down into my protocol.

In order for a staff member’s revised tasks to flow into the protocol, the Delegated Tasks by Staff Role must be edited for the contact BEFORE they are added to the protocol record.

If you are waiting for the staff member to sign their updated tasks at the contact level, remove their tasks and Protocol Staff Role at the protocol level. Once they have signed in their contact record, add the applicable Protocol Staff Role in the protocol record, and their updated signed tasks will populate.

If the PI has already signed the staff member’s tasks in the protocol record, the delegated tasks cannot be edited. For instructions on making a correction to the DoA at the protocol level, see the “Delegation of Authority Log Corrections” section above.

8. I made a mistake and added the wrong role and/or task(s) to my contact record, how do I fix it?

Navigate to Admin > Contacts > Select the intended user > Delegated Tasks by Staff Role:

Delegated Tasks by Staff Role

+ Add Delegated Tasks by Staff Role

Protocol Staff Role ↑	Delegated Tasks	Signature Status	
A Clinical Research Assistant ⬇	Safety Event - Report (8), CRF/ eCRF - Data entry/ Correction (9), CRF/ eCRF - Query Response/Resolution (11) and 2 more	Needs Electronic Signature	✎ Edit ✖ Delete
Clinical Research Coordinator	Perform study assessments (3), Determine subject eligibility (5), Safety Event - Collect Data (6) and 7 more	Electronically Signed	✖ Delete
B Principal Investigator	Perform study assessments (3), Evaluate study assessments (4), Determine subject eligibility (5) and 6 more	Electronically Signed	✖ Delete

[A] If the Delegated Tasks by Staff Role has not yet been electronically signed, edits can be made by simply clicking the Edit icon and making any necessary changes.

[B] If the Delegated Tasks by Staff Role has been electronically signed, the entry must be deleted. Then add a new entry, inclusive of the edits, with the electronic signature requirement.

9. Who can configure/edit Delegated Tasks by Staff Role?

Regulatory Coordinators and Regulatory Managers have permissions to configure/edit Delegated Tasks by Staff Role in a contact record.

Start and Stop Dates

10. What is the difference between the Protocol Staff Start/Stop Dates and the Delegation of Authority Start/Stop Dates?

The Protocol Staff Start and Stop Dates reflect when the staff member needs access to the eReg protocol record in order to manage files, view documents, and/ or electronically sign protocol documents. The Delegation of Authority Start and Stop Dates reflect when the staff member is trained (and IRB approved, if required) and able to participate in the research study. A Protocol Start Date must be entered when adding an eReg user to a protocol. The Delegation of Authority Start Date will automatically default to the Protocol Start Date. However, the DoA Start Date can and should be corrected to reflect when the staff member is trained and able to work on the protocol (see Adding Start Dates section above).



Credential Status

11. Why is my Credential Status 'Incomplete' even though my credentials are filed in eReg and cover the time I was delegated on the protocol?

eReg looks for credentials effective starting from your Protocol Staff Start Date listed in the Staff section of the protocol record. If you do not have a Protocol Staff Stop Date, eReg is looking at credentials effective through today. Protocol-required contact credentials must cover the period from Protocol Staff Start Date through present, or through Protocol Staff Stop Date once entered, regardless of start and stop dates on the Delegation of Authority Log.





Table 1: Delegated Tasks by Staff Role

Task	Clinical Research Assistant	Clinical Research Coordinator	Data Manager	Pharmacist	Pharmacy Technician	Principal Investigator	Regulatory Coordinator / Regulatory Manager	Research Laboratory	Research Nurse	Sub-Investigator
Conduct informed consent		X				X			X	X
CRF/ eCRF - Data entry/ Correction	X	X	X						X	
CRF/ eCRF - Review/ Sign						X				
CRF/eCRF - Query Response/Resolution	X	X	X						X	
Determine subject eligibility		X				X			X	X
Evaluate study assessments						X				X
Investigational Product - Accountability				X	X					
Investigational Product - Destruction/Return				X	X					
Investigational Product - Dispensing				X						
Investigational Product - Preparation				X	X					
Investigational Product - Prescribe						X				X
Investigational Product - Receipt/ Storage				X	X					
IRB/ Ethics Committee - Submission/ Communication		X					X		X	
IVRS/IWRS entry		X	X	X	X	X			X	X
Maintain Investigator Site File/ regulatory documents		X					X		X	
Perform physical exams						X				X
Perform study assessments		X				X			X	X
Research Biospecimens - Process	X	X						X	X	
Research Biospecimens - Ship	X	X						X	X	
Safety Event - Assess causality, attribution and severity						X				X
Safety Event - Collect data		X				X			X	X
Safety Event - Report	X	X	X			X			X	X
Subject recruitment						X				X





Table 2: Delegated Tasks in Reference List

Order	Task
1	Conduct informed consent
2	Perform physical exams
3	Perform study assessments
4	Evaluate study assessments
5	Determine subject eligibility
6	Safety Event - Collect Data
7	Safety Event - Assess causality, attribution and severity
8	Safety Event - Report
9	CRF/ eCRF - Data entry/ Correction
10	CRF/ eCRF - Review/ Sign
11	CRF/ eCRF - Query Response/Resolution
12	Maintain Investigator Site File/ regulatory documents
13	IRB/ Ethics Committee - Submission/ Communication
14	IVRS/IWRS entry
15	Collect Vital Signs/ECG
16	Emergency Unblinding of Subjects
17	Subject education and/or training
18	Subject recruitment
19	Blinded Personnel
20	Unblinded Personnel
21	Apheresis Product - Cryopreservation, sampling, packaging and shipping
22	Investigational Product - Prescribe





Order	Task
23	Investigational Product - Receipt/ Storage
24	Investigational Product - Accountability
25	Investigational Product - Preparation
26	Investigational Product - Dispensing
27	Investigational Product - Administration
28	Investigational Product - Destruction/Return
29	Research Biospecimens - Collect
30	Research Biospecimens - Process
31	Research Biospecimens - Ship
32	Investigational Device - Receipt/ Storage
33	Investigational Device - Accountability
34	Investigational Device - Destruction/ Return
35	Investigational Device - Device Use/ Implantation

Certain tasks should only be performed by a qualified individual as permitted by local law, medical or standard of care practices, or applicable required training as per job description or designation.

Additional Resources

- eReg Guidance Document – Electronic Signatures
- eReg Work Instructions – Delegated Tasks by Staff Role (Master DoA)
- Yale eReg Protocol Import/ Creation Guide
- eReg Learning Portal
- YCCI eReg website: <https://medicine.yale.edu/center-clinical-investigation/research-services/systems/ereg/>

