eReg Guidance Document
Delegation of Authority

Contents

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Acronyms

CRF: Case Report Form

A: Answer

DoA: Delegation of Authority log

ECG: Electrocardiogram

eCRF: Electronic Case Report Form

FAQ: Frequently Asked Questions

IRB: Institutional Review Board

IVRS: Interactive Voice Response System

IWRS: Interactive Web Response System

PI: Principal Investigator

Q: Question

YCCI: Yale Center for Clinical Investigation

General Definition and Information

The Delegation of Authority log (DoA) 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. Staff members and the PI will sign off on their delegated tasks before the staff member performs any work on a study.

To use this feature in eReg, tasks are first assigned to staff members. The tasks are routed for electronic signature by the staff member within eReg. After the staff member signs off on the tasks, the tasks and staff start date are routed to the PI for electronic signature in the protocol record. When the study is complete and ready for closure with the Institutional Review Board (IRB), the DoA will be electronically routed and signed off on by the PI, which will produce the final Delegation of Authority Report.

Tasks assigned to staff members → Staff member verifies and signs off on tasks → Tasks and start dates are routed to PI for sign off → Stop dates are routed to PI for sign off as staff end participation → When study is complete, PI signs off on DoA record

Protocol Import

When a protocol is imported from OnCore into eReg, most of the details will be imported along with it. Sponsor, Department(s), Study Site, and any unique Identifiers are manually added after import, before

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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.
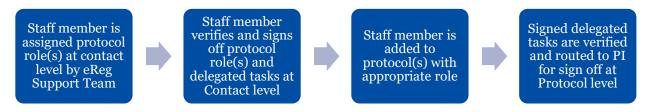
Ensure that the following details are complete and correct as they are included on the Delegation of Authority log report:

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

Delegated Tasks

There are two options for setting up and maintaining a Delegation of Authority log in eReg: Delegated Tasks by Staff Role (Master DoA) and Delegated Tasks Added Individually (Standard DoA). Contact records are created by eReg Support to support the use of the Master DoA, however, either approach can be used. 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.

Delegated Tasks by Staff Role (Master DoA)

Staff member is assigned protocol role(s) at contact level by eReg Support Team	→	Staff member verifies and signs off protocol role(s) and delegated tasks at Contact level	→	Staff member is added to protocol(s) with appropriate role	→	Signed delegated tasks are verified and routed to PI for sign off at Protocol level

The Master Delegation of Authority workflow is oftentimes the most efficient approach for maintaining the Delegation of Authority log. 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 eReg Support Staff in YCCI have defined universal staff roles at the eReg system level that contain a predetermined list of delegated tasks. 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.
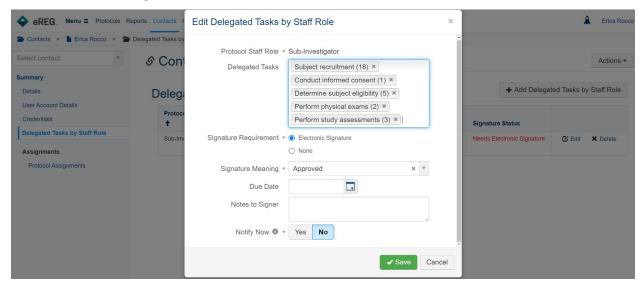
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After a staff role is routed for signature at the contact level, the staff member will sign off on each staff role one time. The delegated tasks associated with the staff role are then inherited by every protocol to which the staff member is added using that role.

Removal/ Addition of Delegated Tasks by Staff Role

If the delegated tasks predetermined by YCCI at the system level by staff role do not align with what the staff member will be doing, delegated tasks can be added or removed at the contact level before they are routed for signature (select Edit for a staff role assigned in the Delegated Tasks by Staff Role section of the staff member's contact record). The staff role is still routed for signature at the contact level so that the staff member only needs to sign off one time. A signature meaning of 'Approved' is used. The delegated tasks associated with the staff role are then inherited by every protocol to which the staff member is added using that role.

Refer to the Learning Portal for more information on how to add or remove delegated tasks by staff role at the contact level.

Delegated Tasks Added Individually (Standard DoA)

Staff member is assigned protocol role and tasks at protocol level by Study Staff → Staff member verifies and signs off delegated tasks at protocol level → Signed delegated tasks are verified and routed with start date to PI for sign off
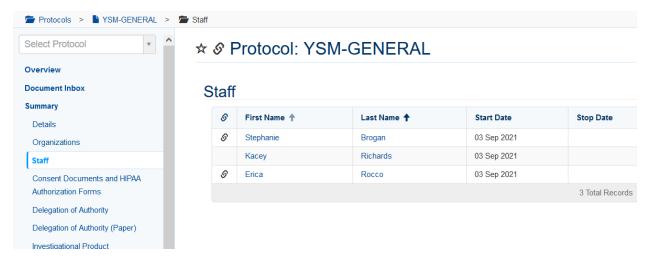
Delegated tasks can be individually added to a staff member at the protocol level. The tasks that can be individually added are selected from a reference list in eReg (see Table 2). These tasks will only be applied to the specific protocol on which they are added and will not be automatically inherited by other protocols to which the staff member is assigned. When using the standard DoA, delegated tasks will have to be assigned to each staff member who is not using role-defined tasks (Master DoA approach) on a protocol. The delegated tasks will also have to be signed off by the staff member and then PI for each protocol to which the staff member is assigned.

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

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

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Custom Delegated Tasks

If a protocol calls for a very specific task that is not available within the reference list in eReg (see Table 2), this task would 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 to Protocol Record section for adding delegated tasks individually. After step (4) selecting Add Delegated Tasks from the actions drop down menu, (5) select Customize.

(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).

Follow the instructions below to route delegated tasks for signature by the staff member and PI.

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.

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

Adding Start and Stop Dates

Adding Start Dates

After your protocol is initially imported into or created in eReg, study staff members will be added to the eReg protocol by a Yale Regulatory Coordinator, Yale Regulatory Manager and/ or PI. All staff members listed in the staff section of the protocol in eReg 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 Delegation of Authority Log Corrections section below.

In order to route protocol documents for electronic signature within eReg, a 'Protocol Staff Start Date' must be applied to their staff listing. If a future date is selected, a user will not be able to access the protocol, route documents for signature nor sign documents until this date occurs. The 'Protocol Staff Start Date' is separate from the 'Delegation of Authority Start Date'.

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Protocol Staff Start Date: The date the staff member has access in eReg to begin viewing and updating the eReg record, and/ or to begin signing documents within the eReg system. Past, current and future dates can be selected. This date must be entered in order to add a Delegation of Authority Start Date.

- Note: Contact credentials are inherited by the protocol based upon the Protocol Staff Start Date and Protocol Staff Stop Date. Protocol-required contact credentials must cover the period from Protocol Staff Start Date to Protocol Staff Stop Date. For this reason, we recommend using a Protocol Staff Start Date when access is needed to view or update the record or to sign documents and avoid using past dates.

Delegation of Authority Start Date: The date the staff member is able to begin working on the study. Past, current and future dates can be selected.

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. active) when determining delegation of authority start dates. For an active study, it is best practice to apply a delegation of authority start date that is the latter date of IRB approval and documented protocol training for staff who require IRB approval. The date of documented protocol training should be used for staff who do not require IRB approval. For studies in start up, it is best practice to apply a delegation of authority log start date equal to the date of study activation at the site for all staff who are IRB approved, if applicable, and have documented protocol training.

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 Delegation of Authority Start Date if the PI has not yet signed off on the Delegation of Authority Start Date. The Delegation of Authority Start Date will often be a different date than the Protocol Staff Start Date; therefore, you must change the Delegation of Authority Start Date prior to routing for PI sign off. Refer to the Learning Portal for more information on how to edit these dates.
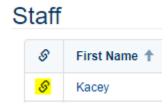
A Delegation of Authority Start Date cannot be changed after the Delegation of Authority Start Date has been signed off on by the Principal Investigator. Ensure the start date is correct before routing staff entries to the PI for signature. See Delegation of Authority Log Corrections section below for more information on how to correct errors in the DoA.

Unlinked Staff Records
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 start dates for unlinked staff records are made directly in eReg. Refer to the Learning Portal for more information on how to add start dates in eReg.

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.

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The start date for linked staff must be entered in the PC Console of OnCore in the protocol Staff section. Dates entered in OnCore flow into eReg and are applied to the delegation of authority log.
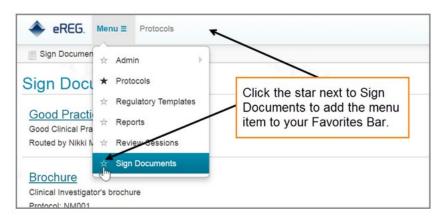
Routing Tasks and Start Dates for PI Signoff

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, (1) 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 (2) 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.

The PI will view requests for sign off on tasks 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 tasks and start dates for PI signoff.

Adding Stop Dates

Staff members must also 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.

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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 end access 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: Contact credentials are inherited by the protocol based upon the Protocol Staff Start Date and Protocol Staff Stop Date. Protocol-required contact credentials must cover the period from Protocol Staff Start Date to Protocol Staff Stop Date.

Delegation of Authority Stop Date: The date the study staff member ends their participation in the study. Past, current and future dates can be selected.

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 Delegation of Authority Stop Date if the PI has not yet signed off on the Delegation of Authority Stop Date. The Delegation of Authority 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. Refer to the Learning Portal for more information on how to edit these dates.

A Delegation of Authority Stop Date cannot be changed after the Delegation of Authority Stop Date has been signed off on by the Principal Investigator. Ensure the stop date is correct before routing to the PI for signature. See Delegation of Authority Log Corrections section below for more information on how to correct errors in the DoA.
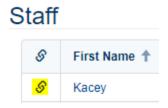
Unlinked Staff Records
Effective 18-Oct-2021, protocol staff are no longer being imported from OnCore to eReg and the staff records are no longer linked. Updates to stop dates for unlinked staff records are made directly in eReg. Refer to the Learning Portal for more information on how to add stop dates in eReg.

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.

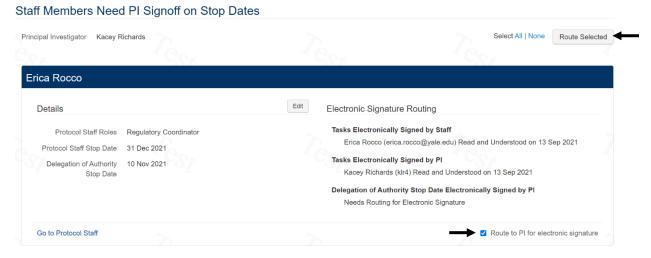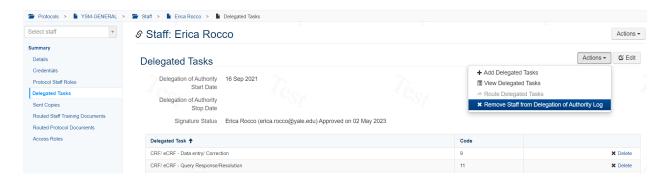Yale Center for
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The stop date for linked staff must be entered in the PC Console of OnCore in the protocol Staff section. Dates entered in OnCore flow into eReg and are applied to the delegation of authority log.

Routing Stop Dates for PI Signoff

To route study member stop dates to the PI, (1) select the "Route to PI for electronic signature" checkbox.

Then (2) 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.

The PI will view requests for sign off on stop date 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.

Delegation of Authority Log Corrections

Removing Staff

It is possible to remove a staff member from the delegation of authority log if that staff member's delegated tasks have not yet been routed to the PI (or if you unroute the tasks prior to PI signature). To remove the staff member from the delegation of authority log, select 'Remove Staff from Delegation of Authority Log' from the Actions button menu in the staff member's record for the protocol.

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

To correct delegated tasks <u>associated with the staff role and/ or delegated tasks assigned in a contact record</u>, (1) delete the current staff role, then (2) add the correct staff role and associated delegated tasks.

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

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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 tab. This stop date 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.

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

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

(6) If necessary, enter the appropriate Delegation of Authority Stop Date in the Delegated Tasks tab of the staff record. This date can also be reviewed and edited as needed in the Delegation of Authority section of the protocol record, prior to PI sign off.

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(7) Route the corrected entry 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.

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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

Routing the Delegation of Authority report for final PI signoff will be done 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". (4) Add a due date or notes to signer (optional).

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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.

Refer to the Learning Portal for more information on how to route the final delegation of authority report to the PI for signoff.

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FAQ

Q: When using the Master Delegation of Authority workflow, do staff members who are assigned additional delegated tasks by role need to re-sign off on tasks at the protocol level?

A: Yes. If additional or custom delegated tasks are added to a staff member after they have signed off on the Master delegated tasks or a staff member is assigned an additional role, the staff member will need to re-sign off on their tasks.

Q: What is the difference between the <u>Protocol Staff</u> Start/Stop Dates and the <u>Delegation of Authority</u> Start/Stop Dates?

A: 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).

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

A: 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	Pharmacist	Pharmacy Technician	Principal Investigator	Regulatory Coordinator	Research Laboratory	Research Nurse	Sub-Investigator
Conduct informed consent		X			X			X	X
CRF/ eCRF - Data entry/ Correction	X	X						X	
CRF/ eCRF - Review/ Sign					X				
CRF/eCRF - Query Response/Resolution	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	
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
Subject recruitment					X				X

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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

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Order	Task
22	Investigational Product - Prescribe
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.

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Additional Resources

- Yale eReg Protocol Import/ Creation Guide
- eReg Learning Portal
- YCCI eReg website: https://medicine.yale.edu/ycci/researchservices/systems/ereg/