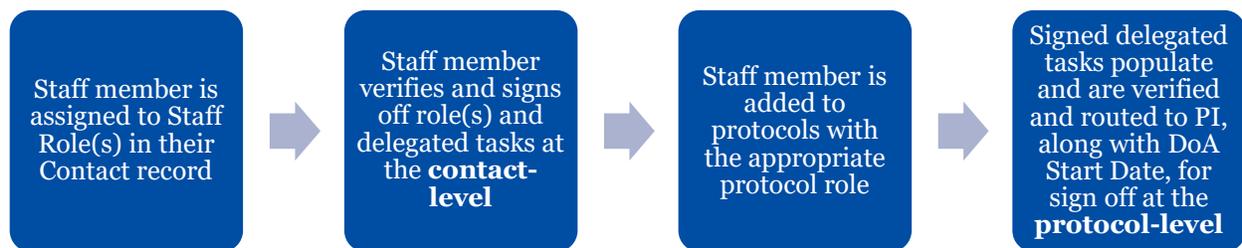


eReg Work Instructions

Master Delegation of Authority / Delegated Tasks by Staff Role

Master Delegation of Authority Workflow in eReg



The eReg system supports a Master Delegation of Authority (DoA) workflow. See eReg Guidance Document – Delegation of Authority for details and FAQs related to the electronic DoA in eReg, including details of the Master DoA workflow. **These working instructions describe how to set up the Master DoA workflow using the eReg tool “Delegated Tasks by Staff Role” in a user’s Contact record.**

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.

Protocol Staff Roles Configured for Use with the Master DoA Workflow

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

Setting Up Delegated Tasks by Staff Role

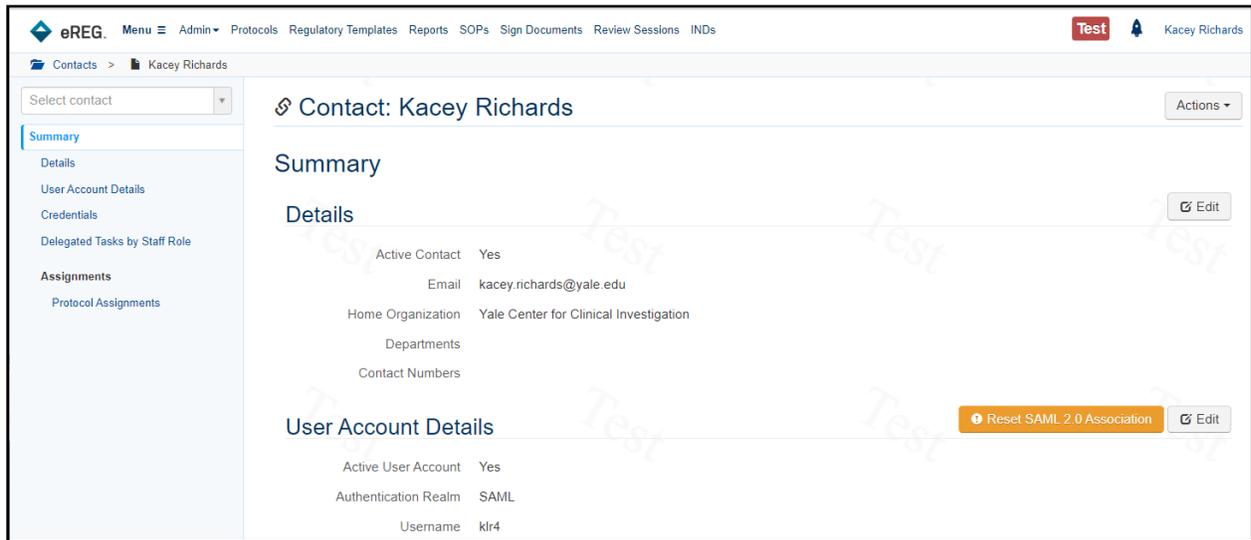
Step 1: Navigate to the user's contact card. Admin > Contacts > Select the intended user



The screenshot shows the eREG interface with the 'Contacts' page. A search bar contains 'kacey'. Below the search bar is a table with the following columns: First Name, Last Name, Home Organization, Active Contact, Active User Account, and Username. One record is highlighted with a red box:

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

Below the table, it indicates '1 Total Record'. On the left side, there are radio buttons for 'Active Contact' with 'Yes' and 'No' options.

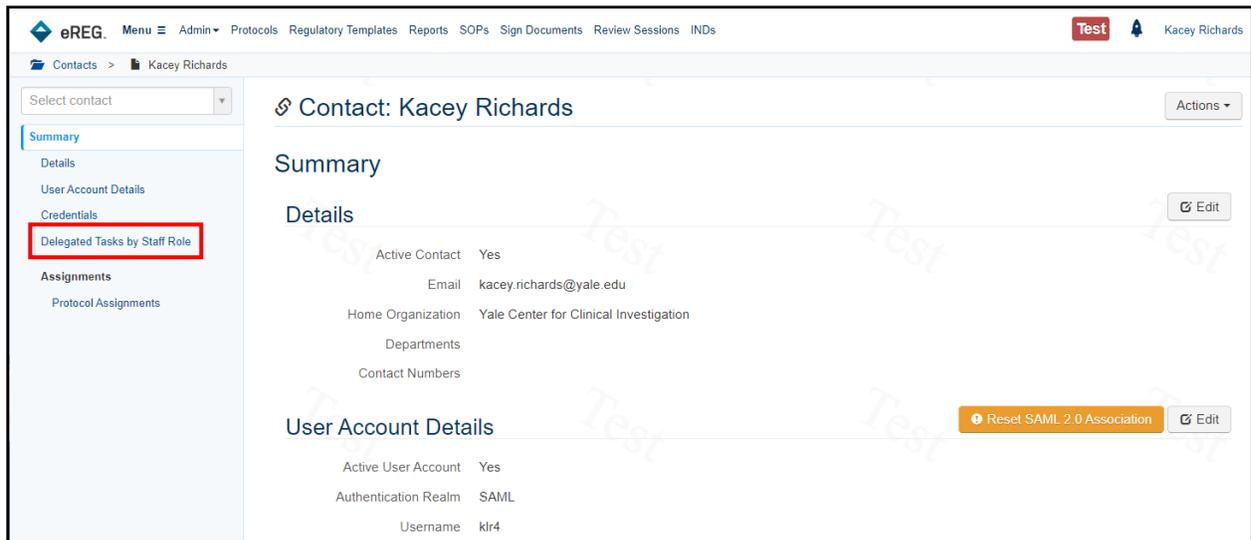


The screenshot shows the 'Contact: Kacey Richards' details page. The left sidebar contains a menu with the following items: Summary, Details, User Account Details, Credentials, Delegated Tasks by Staff Role, Assignments, and Protocol Assignments. The main content area is divided into three sections:

- Summary**: Contains an 'Edit' button.
- Details**: Lists the following information:
 - Active Contact: Yes
 - Email: kacey.richards@yale.edu
 - Home Organization: Yale Center for Clinical Investigation
 - Departments
 - Contact Numbers
- User Account Details**: Lists the following information:
 - Active User Account: Yes
 - Authentication Realm: SAML
 - Username: klr4

At the bottom right of the details section, there is a 'Reset SAML 2.0 Association' button and another 'Edit' button.

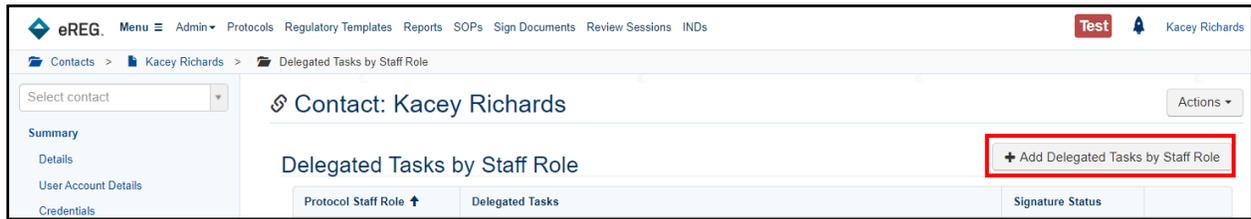
Step 2: Select **Delegated Tasks by Staff Role** in the left pane.



This screenshot is identical to the previous one, but the 'Delegated Tasks by Staff Role' option in the left sidebar menu is highlighted with a red box, indicating it has been selected.



Step 3: Click the **Add Delegated Tasks by Staff Role** button.



Step 4: In the pop-up window, complete all fields.

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

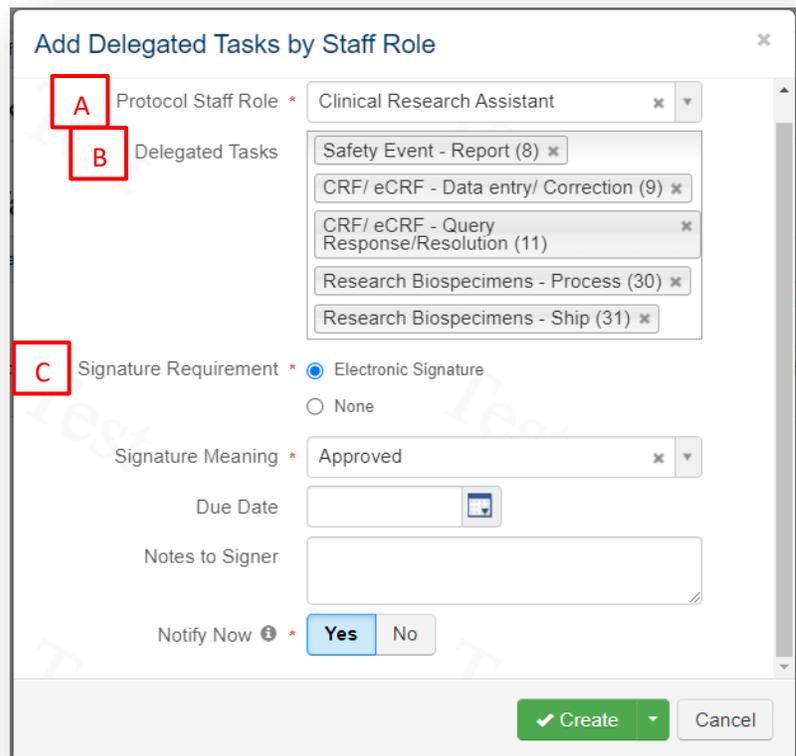
Note- More than one Protocol Staff Role can be configured for a user, if they fill different protocol roles across their studies. Each Protocol Staff Role that is configured will have its own associated tasks.

[B] Delegated Tasks – If you select one of the pre-configured Protocol Staff Roles listed above, the set of delegated tasks (Table 1) 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.



Editing 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.

All edits made to the Delegated Tasks by Staff Role will only flow into protocols the contact is added to AFTER the edits are made. For the electronic signature to flow down into those protocols, the Delegated Tasks by Staff Role must be electronically signed BEFORE adding the user to any protocols.

Who do I contact if I need help with the Delegated Tasks by Staff Role section or the Master DoA workflow?

Please reach out to eReg.support@yale.edu with any questions.

Additional Resources

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



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

