Yale eREG Notice Regarding Delegated Task Changes

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) have made changes to the following Reference Lists in the eReg system:

- Delegated Task

Table 1 below indicates which tasks have been modified (administrative changes), which are new or unchanged (prior task is N/A), and which are no longer available for use (deactivated). If protocol-specific tasks need to be delegated to a study staff member, users with multi-site and regulatory roles can add custom tasks at the protocol level.

The Delegated Tasks by Staff Role have also been updated to better reflect the duties performed by each role (Table 2 below).

What will happen to my existing studies and contact record?
Tasks that have been administratively modified will be updated to the modified task name within your existing protocol records and contact record. However, newly added or removed tasks for a staff role will not automatically be added or removed from the protocol and contact records. Roles and tasks that were previously electronically signed off will remain electronically signed off. If you wish to add or remove new tasks, you will need to manually do so in the protocol and/ or contact record.

The eReg Support Staff are auditing staff roles and delegated tasks by staff role to determine where corrections are needed. Contact records for the following staff will be reviewed and manually updated to reflect the correct tasks:

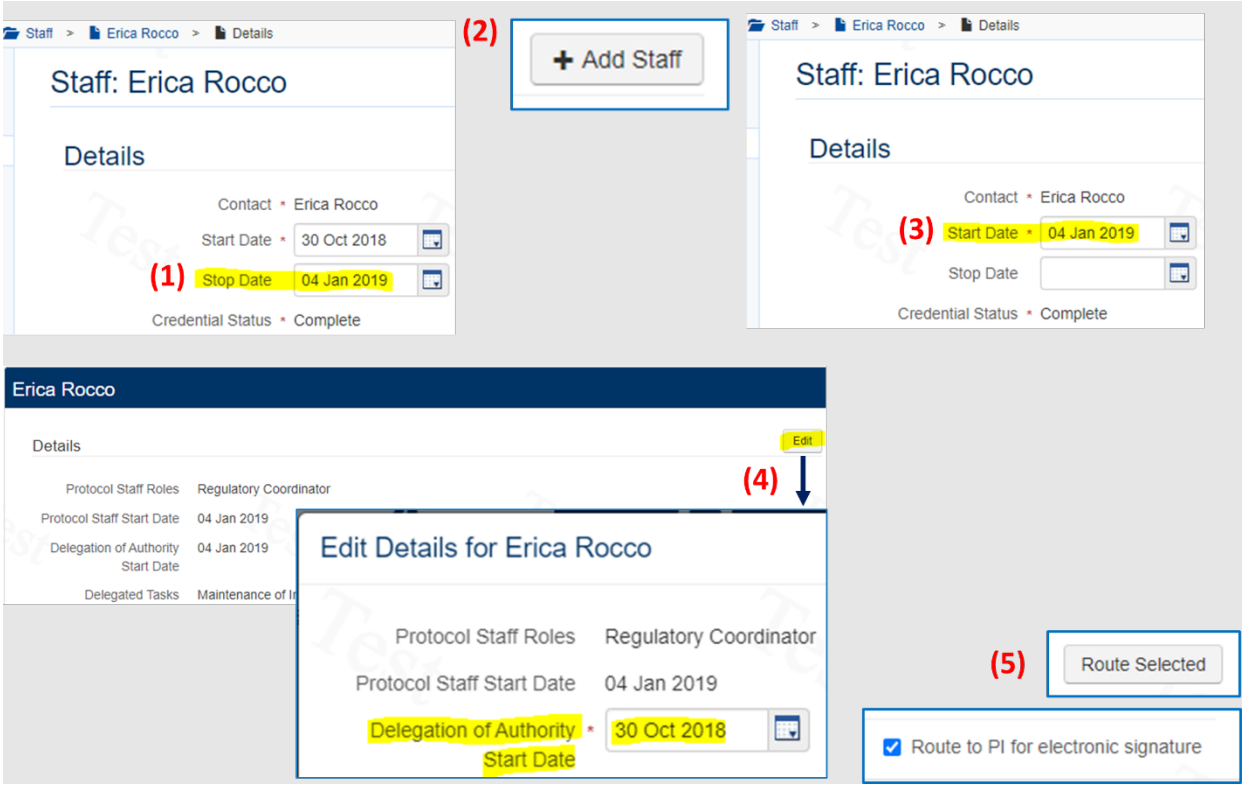
- Principal Investigators
- Sub-Investigators
- Pharmacists
- Pharmacy Technicians
- Research Laboratory

eReg Support will re-route contact-level delegated tasks for electronic signature from users with these roles.

What do I need to do?
Users are asked to review other team members' roles and delegated tasks at the contact record and confirm which, if any, need to be added and/ or removed.

To correct delegated tasks <u>associated with the staff role 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.

To correct delegated tasks 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, then (2) re-add the staff member in the Staff tab with a Start Date equal to the Stop Date entered for the original entry (3). Confirm the Delegated Tasks are correct and approved by the staff member. (4) Correct the Delegation of Authority Start Date in the Delegation of Authority section of the protocol record, then (5) route the corrected entry to the PI for electronic signature.



Moving forward, Staff Role(s) and relevant Delegated Task(s) will be identified during the User Access Request process.

Delegation of Authority Start & Stop Dates

Users are no longer able to import protocol staff from OnCore (see 'Yale eREG Notice Regarding User Role Changes' sent on 18-Oct-2021). For protocols currently in eReg, start and stop dates for linked staff (icon highlighted below) will continue to be managed in the PC Console in OnCore.

Start and stop dates for staff manually added moving forward will not have the linked icon highlighted above and will be managed in the protocol record in eReg by editing the staff member's Details page.

Who do I contact with questions?
Please contact eReg Support (eReg.Support@yale.edu) with any questions.

Table 1

Reference List – Delegated Task

New Order	New Task	Prior Task
1	Subject recruitment	Perform subject recruitment
2	Conduct informed consent	Conduct and/or obtain informed consents
3	Determine subject eligibility	N/A - No change made
4	Perform physical exams	N/A - No change made
5	Perform study assessments	N/A - No change made
6	Evaluate study assessments	N/A - No change made
7	Safety Event - Collect data	Collect AE/SAE data
8	Safety Event - Assess causality, attribution and severity	Assess AE/SAE causality, attribution and severity
9	Safety Event - Report	Report Serious Adverse Events
10	CRF/ eCRF - Data entry/ Correction	CRF/ query completion and correction
11	CRF/ eCRF - Review/ Sign	CRF/ query signature
12	CRF/eCRF - Query Response/Resolution	N/A - New Task
13	Maintain Investigator Site File/ regulatory documents	Maintenance of Investigator Site File/ regulatory documents

14	IRB/ Ethics Committee - Submission/ Communication	IRB submissions and communications
15	Investigational Product - Receipt/ Storage	N/A - New Task
16	Investigational Product - Accountability	N/A - New Task
17	Investigational Product - Prescribe	Prescribe Investigational Product
18	Investigational Product - Preparation	N/A - New Task
19	Investigational Product - Dispensing	N/A - New Task
20	Investigational Product - Administration	N/A - New Task
21	Investigational Product - Destruction/Return	N/A - New Task
22	Research Biospecimens - Collect	N/A - New Task
23	Research Biospecimens - Process	N/A - New Task
24	Research Biospecimens - Ship	N/A - New Task
25	Investigational Device - Receipt/ Storage	N/A - New Task
26	Investigational Device - Accountability	N/A - New Task
27	Investigational Device - Destruction/ Return	N/A - New Task
28	Apheresis Product - Cryopreservation, sampling, packaging and shipping	Cryopreservation, sampling, packaging and shipping of apheresis product
29	Collect Vital Signs/ECG	N/A - No change made
30	IVRS/IWRS entry	N/A - No change made
31	Subject education and/ or training	Train Subjects to use study related equipment and/or tasks
32	Unblinded Personnel	N/A - No change made
33	Blinded Personnel	N/A - No change made
34	Emergency Unblinding of Subjects	N/A - No change made
	N/A - Deactivated	Case Report Form (CRF) Completion
	N/A - Deactivated	Collect and/or Process and/or Ship research lab samples
	N/A - Deactivated	Data Entry
	N/A - Deactivated	Investigational Product (IP)/ Device storage and accountability

	N/A - Deactivated	IP preparation and/or dispensation and/or Administration
	N/A - Deactivated	Modified Rankin
	N/A - Deactivated	NIHSS
	N/A - Deactivated	Receipt, storage, preparation of investigational product
	N/A - Deactivated	Shipping, packaging, receipt, storage and preparation of product

Table 2

Delegated Tasks by Staff Role

	Staff Role								
Delegated 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