

Yale eReg Notice Regarding Changes to Delegated Tasks by Staff Role

Dear eReg User,

The eReg Support team in the Yale Center for Clinical Investigation (YCCI) have made the following changes to the Delegated Tasks by Staff Role in the eReg system:

- 1. Added Data Manager Protocol Staff Role, with associated tasks:
- CRF/eCRF Data entry/ Correction (9)
- CRF/eCRF Query Response/Resolution (11)
- IVRS/IWRS entry (14)
- Safety Event Report (8)
- 2. Added Regulatory Manager Protocol Staff Role, with associated tasks (same as Regulatory Coordinator role):
- Maintain Investigator Site File/ regulatory documents (12)
- IRB/ Ethics Committee Submission/ Communication (13)
- 3. Added IVRS/IWRS entry (14) task to the following Protocol Staff Roles:
- Principal Investigator
- Sub-Investigator
- Research Nurse
- Clinical Research Coordinator
- Data Manager
- Pharmacist

Pharmacy Technician

Reminder: Tasks can be edited at the contact-level and at the protocol-level prior to routing the staff entry to the PI for electronic signature.

What will happen to my existing studies and contact records?

The new "Data Manager" and "Regulatory Manager" Protocol Staff Roles can be selected for study team members moving forward. **Existing studies and contact records will not be impacted by this change.**

The "IVRS/IWRS entry" task will appear as one of the default delegated tasks when the above Protocol Staff Roles are selected for study team members moving forward. The task can be removed prior to PI sign-off if necessary. The task will not automatically be added to existing protocol staff and contact records. Roles and tasks that were previously electronically signed off will remain electronically signed off. If you wish to add the task, you will need to manually do so in the protocol and/ or contact record.

What do I need to do?

Users are asked to review their/their team members' roles and delegated tasks in the Contact record > Delegated Tasks by Staff Role and confirm which, if any, need to be added and/ or removed.

For detailed instructions on correcting delegated tasks, please review the <u>YCCI eReg Guidance</u> <u>Document – Delegation of Authority</u>, sections:

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

This updated guidance document will be posted to the YCCI eReg website in the coming weeks.

Who do I contact with questions?

Please contact eReg Support (ereg.support@yale.edu) with any questions.

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