Yale eReg Notice Regarding User Role Changes

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) are revising the eReg User Roles to better support how Yale staff and external monitors/auditors are accessing and utilizing the eReg system. There are two major changes to user role configuration:

- Users are no longer able to import protocol staff from OnCore. Instead, the 'Add Staff' tool is used to add individual staff members to a protocol in eReg.
- The ability to view and/or access protocols at a global level has been restricted, and new user roles are created to accommodate department-level access. Users with a department-driven role will be able to access protocols assigned to their department(s), even if they are not listed as a study staff member.

Examples of other changes are as follows:

- Both Yale Regulatory Coordinator and Yale Regulatory Manager roles have been modified to allow use of custom tasks at the protocol-level.
- Ability to lock protocols has been added to the Yale Regulatory Manager role.
- YCCI Reviewers can view the protocol outline for a multi-site protocol, in order to see required credentials.
- SOP Review functionality has been added to multiple user roles.

What do I need to do?

The eReg Support staff are auditing the current role(s) assigned to each active eReg user, to determine where contact records need updating. eReg Support may reach out to you with questions about your use of eReg to ensure the appropriate role is assigned.

For new studies moving forward, the appropriate User Role(s) will be identified during the User Access Request process.

Will my access to protocols be affected?

eReg users will continue to be able to see protocols to which they are assigned as study staff and will retain many of the same system permissions. eReg users with certain manager-level or read-only user roles will also be able to see protocols assigned to their department, even if they are not a study staff member. Regulatory and Multi-Site roles will now have tiered levels of access and permissions, and current users may be reassigned to a different tier more appropriate for their day-to-day work.

As you and your teams continue working in the eReg system, please contact eReg Support (<u>eReg.Support@yale.edu</u>) if a user's permissions are restricting them from fulfilling their duties. eReg Support will determine if any changes are needed to the protocol's department assignment, user's contact department assignment, and/or the user's role.

Who do I contact with questions?

Please contact eReg Support (<u>eReg.Support@yale.edu</u>) with any questions.