



Electronic Regulatory (eReg) Management System Access Guide

1.0 Overview

All Yale University/YNHH employees and third-party personnel must complete proper training before being granted access to the Advarra eRegulatory (eReg) system. Yale/YNHH employees must also have current credential documents before being granted access to eReg.

Existing users may require additional training or credential types due to an update in the system, a change in system procedures, or a change in the User's role(s).

2.0 OnCore Access

Before granting eReg system access to Yale University/YNHH employees and consultants, one must first establish an account in Yale School of Medicine's clinical trials management system (OnCore). Third-party monitors and reviewers do not need to establish an OnCore account.

To establish an OnCore account, please refer to the [YCCI OnCore website](#) for access forms and directions.

3.0 eReg System Access Procedures

To obtain eReg access, a user must have the following items:

All Users: 1) Completed eReg User Access Request form and 2) Completed eReg system training

Internal Yale/YNHH Users Only: 3) Completed Signature Sample form; 4) Good Clinical Practice (GCP) Training Certificate and 5) CV and/or ML (if applicable to their role)

Certain Internal eReg User Roles: 6) Completed YCCI content-specific training

3.1. eReg Access Request Form:

A new user (or a current user updating their user role) will complete the online eReg Access Request form. The link to the online eReg Access Request form is located on the [YCCI eReg website](#).

Once the online request form is submitted, the eReg Support team will contact the user with their required training and credentials as needed.

3.2. eReg System Training:

3.2.1. Computer-based eLearning

The eReg system training is role specific. The computer-based eLearning occurs in Advarra University: <https://advarrauniversity.learnupon.com/dashboard>. This is the most common and preferred way of providing system training for Advarra eReg. Once an access request form has been completed, an Advarra University account will be created for the user and the appropriate role-specific training will be set up. eReg Support will email the new user with instructions on how to access the training.

Once Advarra University training is complete, the user should notify eReg Support (ereg.support@yale.edu). Depending on the user role requested, additional training and credential documents may be required by YCCI before an eReg account can be established/updated.

3.3. eReg Content Training:

3.3.1. In-person/Virtual Training with YCCI





Certain user roles require additional content-specific training conducted by YCCI. Once a user submits the online eReg Access Request form, eReg Support will assess whether content-specific training is required. If YCCI content-specific training is required, the user will be enrolled in the next available training. The user will be notified of the date and time of the YCCI training once enrolled.

3.3.2. User Roles Requiring YCCI Content-Specific Training

The following user roles will require both system training and content-specific training:

- Yale Regulatory Coordinator
- Yale Regulatory Manager
- Multi-Site (Assigned)
- Multi-Site (Department)
- Administrator

3.4. Signature Sample:

All Yale University/YNHH employees and consultants will submit a Signature Sample form. This form is required prior to account activation and will be uploaded into each user's contact card in eReg. A scanned copy of the completed form should be emailed to eReg Credentials (ereg.credentials@yale.edu). The Signature Sample form is located on the [YCCI eReg website](#).

3.5. Good Clinical Practice (GCP) Training Certificate:

All Yale University/YNHH employees and consultants are required to have a current Good Clinical Practice training certificate on file in eReg prior to account activation. The eReg Support staff have access to GCP training certificates for Yale University employees. YNHH employees and consultants will need to email a copy of their GCP training certificate to eReg Credentials (ereg.credentials@yale.edu). GCP training certificates will be uploaded into each user's contact card in eReg. GCP training expires three years from the training completion date.

3.6. Curriculum Vitae (CV):

Any user who identifies as a Principal Investigator (PI) or Sub-Investigator (Sub-I) on the eReg access request form are required to have a CV on file in eReg prior to account activation. eReg Users can electronically sign their CVs in the eReg system, so either a Word or PDF version of the CV will be accepted. CVs will need to be emailed to eReg Credentials (ereg.credentials@yale.edu). CVs will be uploaded in the user's contact card in eReg and routed to the user for electronic signature, if needed. CVs expire two years from the signature date.

3.7. Medical License:

Any user who identifies as a licensed medical person (Physician, Research Nurse, etc.) are required to have a current medical license on file in eReg prior to account activation. The eReg Support staff have access to medical licenses and will upload a copy into the user's contact card. Medical licenses expire annually on the last day of the licensee's birth month.

