



## 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 System Contact Record

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

If an OnCore contact record does not exist for the user at the time of requesting eReg access, the eReg Support team will create one.

### 3.0 eReg System Access Procedures

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

**All Internal Users:** 1) Completed eReg User Access Request form; 2) Completed Signature Sample form; 3) Completed eReg system training; 4) Current Good Clinical Practice (GCP) Training Certificate and 5) Current CV and/or ML (if applicable to their role)

**\*Internal eReg Users Requesting the Regulatory Coordinator/Manager Role:** 6) Completed YCCI content-specific training

**All External Users (ex. Sponsor monitors):** 1) Completed eReg User Access Request Form and 2) Completed Advarra University training; No credentials are required.

#### 3.1. eReg User Access Request Form:

A new user (or a current user updating their user role) will complete the online eReg User Access Request form. The link to the online eReg User 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.learnapon.com/dashboard>. This is the most common and preferred way of providing system training for Advarra eReg. Once a user access request form has been completed, an Advarra University account will be created for the user, as applicable, and the appropriate role-specific training will be assigned. eReg Support will email the new user with instructions on how to access the training.

Once Advarra University training is complete, Advarra notifies eReg Support the following business day. 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-Specific Training:

#### 3.3.1. YCCI Content-Specific Training

Certain user roles require additional content-specific training conducted by YCCI. Once a user submits the online eReg User Access Request form, eReg Support will assess whether content-specific training is required. If YCCI content-specific training is required, eReg Support will send the user instructions on how to register themselves for the training. Once the YCCI content-specific training has been completed, the eReg Support team will create/update the user's eReg record.

#### 3.3.2. User Roles Requiring YCCI Content-Specific Training

The following user roles will require both system training and YCCI 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 record in eReg. A scanned copy of the completed form should be emailed to eReg Credentials ([ereg.credentials@yale.edu](mailto:ereg.credentials@yale.edu)). The Signature Sample form is located on the [YCCI eReg website](#). The completed Signature Sample does not expire. However, if a user changes their name/signature used on research documents, they should complete a new Signature Sample form and provide to [ereg.credentials@yale.edu](mailto:ereg.credentials@yale.edu) for filing.

#### 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. All internal users should email a copy of their GCP training certificate (from CITI or Workday Learning) to eReg Credentials ([ereg.credentials@yale.edu](mailto: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 User Access Request form is 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](mailto:ereg.credentials@yale.edu)). CVs will be uploaded in the user's contact record in eReg and routed to the user for electronic signature, if needed. CVs expire two years from the signature date.

#### 3.7. Medical License (ML):

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

