1.0 Overview
All Yale University employees and third-party personnel must complete proper training before being granted access to the Advarra eRegulatory (eReg) system.

Existing users may require additional training 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 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

Certain eReg User Roles: 4) Completed YCCI content-specific training

3.1. eReg Access Request Form:
A new user (or a current user updating their user role) will need to complete an 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.

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 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 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.