West Virginia Clinical Trials Center of Excellence

STANDARD OPERATING PROCEDURE

Title:	No.: COE-123.00	
eReg **Training and Access**	Page 1 of 3	
	Date of Issuance: 16 APR 2021	Date Effective: 17 MAY 2021
	Supersedes: NA	

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Purpose:

This procedure describes processes and documentation necessary for ensuring that Users have the qualifications and training to gain access for their assigned roles in the Advarra eReg system.

Scope:
This procedure applies to the training and access procedures of West Virginia University Employees and third-party personnel for use of the Advarra eReg system.

Materials:
Attachment 1- Internal Training/Access Request Form

Responsibility:

This SOP applies to the HSC Institutions and associated clinical departments actively engaged in clinical research involving human subjects.

Procedure:

A. General Training Requirements

Training may be carried out in any of the following formats:

- Self-review of a document and execution of a Read and Understood Acknowledgement on Attachment 1
- Computer-based self-study training

- Instructor-led training (in person) or online video and execution of a Read and Understood Acknowledgement on Attachment 1

Instructor-led training shall be carried out by a qualified individual.

After completion of the training, the Employee will complete Attachment 1 and forward it to an eReg Administrator (eRegAdmin@hsc.wvu.edu), with a copy to the appropriate manager, as applicable. Supporting evidence of the training should be attached to the record if available.

A certificate, sign-in sheet, or other training record with sufficient detail that is provided by a training system or an Instructor may be used in lieu of the Internal Training Record form.

Personnel that author or approve a formal procedure do not require training on it.

The eReg Adminsitrator(s) will maintain access records for the system.

B. Initial Employee Training

A new User may not be granted access to the system until all training identified on the Training Matrix in Appendix A for that User's intended role(s) has been completed. Evidence of training completion will be forwarded to the eReg Coordinator(s) with the User's access request per the procedures in SOP-EREG-001, eReg System Administration.

C. Ongoing Employee Training

Existing Users may require additional training due to a change in the system, a change in system procedures, or a change in the User's role(s).

The eReg Administrator(s) will notify the applicable Managers and Process Owner when changes are made to the system that may require an SOP update or additional training.

The Process Owner will notify the eReg Administrator(s) and applicable Managers when a new or updated system SOP that requires training is approved.

An existing User may not be assigned a new role in the eReg system until all training identified on the Training Matrix in Table A for that User's new role has been completed. Evidence of training completion will be forwarded to the eReg Administrator with an access request documenting the role modification per the procedures in the eReg Administration SOP.

Managers will notify the impacted Employees of new training requirements and a target date for completion. Managers are responsible for tracking the training requirements to completion and sending out reminders to Users.

All new system training requirements will be reported to the Process Owner for updates to this procedure as needed.

Training/User Role Matrix:

Role	[Forte eReg 100: Navigation]	[Forte eReg: Managing Contact Records]	[Forte eReg: Maintaining Reference Lists]	[Forte eReg: Managing Organization Records]	[Forte eReg: Managing Regulatory Templates]	[Forte eReg: Protocol Management]	[Forte eReg: Managing Documents]	[Forte eReg: Creating Review Sessions]	[Forte eReg: Delegation of Authority]	SOP COE-123.00 Forte eReg Training/Access
Regulatory User	x	x	x	x	x	x	x	x	x	x
Principal Investigator*	x						x		x	x
Reviewer**	x								x	x

*The Principal Investigator role represents signatory and review access only and may apply to Study Coordinators or other research team members as appropriate.

**The reviewer role may apply to internal and external reviewers.

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP

WestVirginiaUniversity.

Clinical Trials Center of Excellence
WVCTSI

eReg Access Request
Version 2.0 01MAR2021

First Name: _____ Last Name: _____

Employed by (check one) WVURC ___ WVUM ___ WVU ___ Other _____ *(specify)*

Work Email: _____

Work Phone: _____ Ext: _____

Department: _____ Title: _____

Credentials (check one): MD ___ DO ___ PhD ___ PharmD ___ RN ___ Other _____ *(specify)*

eReg Role Requested: (check one)

Principle Investigator ___ Regulatory ___

Protocol staff ___ Other _____ *(specify)*

I agree to abide by Federal and Institutional HIPPA and HITECH guidelines and related activities concerning data and patient information.

I acknowledge that I have read and understood the training material provided.

Signature: _____ Date: _____

Authorized Requestor Name: _____ Phone: _____

Authorized Requestor Signature: _____ Date: _____

Authorized Requestor must notify the eReg Administrator, via email at eRegAdmin@hsc.wvu.edu, when the employee leaves this role so their access can be deactivated.

For Office Use Only

Role: _____

Start date in system: _____

Date training completed: _____ **Entered by:** _____