West Virginia Clinical Trials Center of Excellence

STANDARD OPERATING PROCEDURE

Title:		No.: COE-122.00	
Advarra eReg System Administration		Page 1 of 4	
		Date of Issuance: 16 APR 2021	Date Effective: 17 MAY 2021
		Supersedes: NA	
Prepared by: 09 APR 2021 Shelley Welch, RN, MSHS	Reviewed by: 09 APR 2021 Tanya Moran, MS	Approved by: 15 APR 2021 Sally L. Hodder, MD	

Purpose:

This standard operating procedure describes procedures for administration of the eReg in use at West Virginia University.

Scope:
This procedure applies to administrative activities performed in the eReg West Virginia University employees and third-party personnel with administrative access to the system.

Refer to the user manual for specific tasks not identified in this SOP.

Materials:

NA

Responsibility:
This SOP applies to all personnel involved in the conduct or supervision of human subject clinical trials.

Definitions

Protocol – In eReg, this is a grouping of organizations, staff, and folders for management of URLs, documents, and other information for a single clinical protocol.

Regulatory Template – In eReg, this is a template with predefined requirements for organizations and staff, and predefined folder layouts that will pre-populate in a protocol that is created from the template.

Procedure:

A. General

A User will log in to the Production instance of the system with their user ID and password via their browser.

When a User encounters an issue with the system or needs support, they should contact the Application Coordinator(s) at eRegAdmin@hsc.wvu.edu.

B. Access Audits

At least annually, the Application Coordinator(s) will initiate a review of user accounts, roles, and permissions to ensure that system access is set up correctly. This process will involve collaboration with the regulatory staff and comparison against past access requests.

The Application Coordinator(s) will work to resolve any issues identified, consulting with Managers as needed, and make any necessary changes to system access.

The Application Coordinator(s) will document the execution and results of the audit, including any updates made to system access. An Access Audit Form is available to document the audit. The Application Coordinator(s) will store documentation of the audit.

C. Audit Trail Review

At least annually, a review shall be performed on the audit trail records in the system that have been generated since implementation or the previous year's audit. A risk assessment shall be performed to identify areas within the audit trail that are required to be audited based on the level of risk identified. This review of the risk will be documented in a "Risks Identified" section of the risk mitigation form.

The Application Coordinator(s) will work with the regulatory staff to review the audit trail records and investigate any issues identified, consulting with other personnel as needed.

The Application Coordinator(s) will document the execution and results of the review, including attaching a copy of the audit trail records. The results of the audit will be documented in the "Risk Mitigation Activity" section of the Risk Mitigation Form.

The Application Coordinator(s) will store documentation of the review.

D. Administrative Contacts

1. Reference Lists

When a User identifies a required update to a reference list in the system, they will communicate the requested change to the Application Coordinator(s).

2. Contact Management

When a User identifies the need for a new contact or update to an existing contact, they will communicate the requested change to the applicable Regulatory Manager, Regulatory Coordinator, or Application Coordinator(s).

3. Organization Management

When a User identifies a need for a new organization record, they will communicate the requested change to the Application Coordinator. When a User identifies a need for an update to an organization record, they will communicate the requested change to the applicable Regulatory Manager, Regulatory Coordinator or Application Coordinator(s).

4. Regulatory Templates

When a User identifies the need for a new regulatory template or an update to an existing regulatory template, they will communicate the requested change to the Application Coordinator(s).

E. Electronic Signature Meaning

When a User routes a document within eReg, the User must ensure the appropriate signature meaning has been selected before the document is sent for electronic signature.

F. Business Continuity

During downtime, or in any cases where a User cannot access the system due to other reasons, they should use the following procedures.

Note: Since the system is hosted, disaster-recovery procedures are implemented and managed by the vendor.

Any issues with accessing the system should be reported. Contact the Application Coordinator(s) at eRegAdmin@hsc.wvu.edu.

When a User cannot access the system, they may continue to capture documents and route for hardcopy (i.e., wet) signature as needed. Such data and documents can be temporarily stored, either in hardcopy or as a scanned copy. When system access is restored, the documents will be loaded into the system with notation that they were signed via wet signature. If hardcopy templates are needed, the Clinical Trial Center of Excellence should be contacted.

Users will be responsible for maintaining up-to-date versions of critical documents needed for their local operations, either in hardcopy or stored in another electronic system.

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP