West Virginia Clinical and Translational Science Institute
Clinical Trials Center of Excellence

STANDARD OPERATING PROCEDURE

Title:	No.: COE-107.00	
OnCore™ Access	Page 1 of 2	
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Prepared by:	Reviewed by:	Approved by:
09APR 2021	09 APR 2021	17APR2021
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Purpose:

This standard operating procedure (SOP) describes the procedures related to granting user access to the Advarra OnCore™ clinical trial management system.

Scope:

OnCore is the Clinical Trials Management System for all clinical trials conducted at Morgantown Campus of West Virginia University. Anyone accessing OnCore™ to input or utilize information for research purposes will be required to request access.

Clinical research management, for which OnCore™ is a critical component, is a system of tools and processes that supports efficient research operation, facilitates compliance, and streamlines the flow of information, institutional tracking and oversight.

Materials:

Attachment 1- OnCore™ access request form
Attachment 2- User access matrix

Responsibility:

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

Procedure:

A. An OnCore™ access request form must be completed and provided to a system administrator using the following email address:

   OnCoreAdmin@hsc.wvu.edu

   For OnCore clinical protocol requests such as adding sponsors, contacts, etc. use the following address:

   ClinicalTrialsAdmin@hsc.wvu.edu

B. Completion of basic OnCore™ training is required for access to OnCore™. Due to OnCore™ containing Protected Health Information (PHI), all users must also have current HIPAA training to have access to the system.

C. Once training is complete, an OnCore™ administrator will provide a user with access to the appropriate management group and access levels based on the request.

D. Procedures to limit access within OnCore:

   a. Protocols will be linked to a management group based on the department/institute managing the trial. Users will be provided access to specific management groups based on the information on the request form.
   b. Different levels of user access are setup in OnCore™ based on user roles according to Attachment 2.

E. Maintenance of OnCore™ users

   a. The authorized requestor/supervisor for each user is responsible for notifying the OnCore administrators of employee departure. The OnCore administrators will then disable the user access.
   b. A report will be run by the system administrators every 6 months that will list users that have not logged into OnCore in the past 120 days. These users will be inactivated, disabling their login to OnCore. The purpose is to ensure only active employees have access to the system. This report will be kept with the system files.

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP

WestVirginiaUniversity.

Clinical Trials Center of Excellence
WVCTSI

OnCore Access Request

First Name: _____ Last Name: _____

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

Work Email: _____

Work Phone: _____ Ext: _____

Fax: _____ Pager: _____

Department: _____ Title: _____

Credentials: (check one): MD ☐ PhD ☐ DO ☐ PharmD ☐ RN ☐ Other ____

College/Division: _____ PO Box: _____

Work Address: _____

City: _____ State: _____ Zip: _____

Clinical Trials Role (check one):

PI ☐ Co-Inv. ☐ Study Coordinator ☐ Data Manager ☐ Regulatory ☐ Pharmacy ☐

Accounting ☐ Other- (specify reason for access): _____

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

Signature: _____ Date: _____

Authorized Requestor Name: _____ Phone: _____

Authorized Requestor Signature: _____ Date: _____

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

For Office Use Only
Role: _____
Management Group(s): _____
Date Training Completed: _____

COE-106.00 Attachment 2

OnCore User Matrix

Role	Permissions
Principal Investigator	***Protocols***
	• View protocol information and associated documents
	Subjects
	• View subject information
	Calendars
	• View protocol calendars and subject calendars
	Other
	• Perform protocol/subject/document searches
Study Coordinator (Primary or Backup)	***Subjects***
	• Add new subjects to protocols
	• Update subjects protocol statuses
	• Record subject visit updates
	• Assign/update treatment arm
	• Update protocol
	• Enter deviations
	Protocols
	• Enter a new protocol
	• Update accrual goal information
	Other
	• Protocol and Subject search
	• Update task lists
Research Manager	***Subjects***
	• Add new subjects to protocols
	• Update subjects protocol statuses
	• Record subject visit updates
	• Assign treatment arm
	• Update protocol
	• Enter deviations
	Protocols
	• Enter a new protocol
	• Update accrual goal information
	• Open to Accrual
	Financials
	• View Financial information
	Other
	• Protocol and Subject search
	• Update task lists
	• Run Reports
Data Manager	***Protocols***
	• View protocol information and associated documents
	Subjects

OnCore User Matrix

	• Add new subject information and status • Update treatment ***Other*** • Update task lists • Protocol and Subject search
Regulatory (Primary or Backup)	***Protocols*** • Create new and update protocols • Submit protocols for feasibility reviews • Update status of feasibility reviews • Update protocols closed to accrual, on hold, suspended status • Designate a protocol as 'Terminated' or 'Abandoned' ***Other*** • Update staff on protocol • View audit/monitoring findings • Run reports • Perform protocol/subject/document searches • Update tasks lists
Pharmacy	***Subjects*** • View subjects ***Protocols*** • View protocol documents ***Other*** • Run reports • Update task lists
Accounting	***Financials*** • Create a new protocol budget versions • Update coverage analyses • Write-off outstanding balances on invoices • Update invoices, invoice number, invoiceable items, invoicing rules, milestones, and visit variations • Create new protocol budget versions • Update protocol and subject-related budget items • Update receipts • Reconcile invoices ***Calendars*** • View protocol calendars (including unreleased calendars) and subject calendars ***Subjects*** • View subjects • View subject calendar visits ***Other*** • Perform protocol/subject/document searches • Run reports

OnCore User Matrix

	• Update task lists
System Administrator	***Subjects***
	• Global access
	Protocols
	• Global access
	Financials
	• Global access
	Calendars
	• Global access
	Other
	• Global access
Quality Assurance	***Audits***
	• Audit / Monitoring Findings and Setup
	Subjects
	• View Subjects (if assigned to management group)
	• View Subject Calendars (if assigned to management group)
	Protocols
	• View Protocols and associated documents
	Other
	• Run Reports