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

STANDARD OPERATING PROCEDURE

Title:		No.: COE-106.00	
Utilization of OnCore for Clinical Research		Page 1 of 2	
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Purpose:

This standard operating procedure (SOP) describes the policies and procedures followed at this investigative site (West Virginia University, WVU) for the utilization of Forte OnCore™, the institutional clinical trial management system that has been implemented to manage clinical research and facilitate fiscal and operational compliance.

Scope:

All clinical trials conducted at the Health Sciences Center of West Virginia University shall be registered in OnCore™. For the purpose of this SOP, a clinical trial shall meet the NIH definition: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. This applies to all clinical trials where human subjects are included regardless of the source of funding.

The use of a single institutional clinical trials management system will promote the safety of study participants and allow for greater efficiency in conducting studies. This policy provides guidance to ensure consistency and best practices in the management of clinical studies with the use of OnCore™.

Materials:

NA

Responsibility:

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

Procedure:

A. Minimum footprint of OnCore™ use for all Clinical Trials:

1. All required fields in the protocol console completed (PC console) with system signoffs and participating affiliated institutions
2. Regulatory approval events (ie. Initial IRB approval, amendments and continuing reviews) completed
3. Registration of all Consented Subjects in CRA Console
4. Accurate study status to ensure proper display on public WVU Clinical Trial search feature. https://www.hsc.wvu.edu/ctru/current-clinical-trials/search/
5. Protocol and subject deviations, including reports for appropriate reporting
6. Safety reporting of Serious Adverse Events, including completed printed report
7. Regulatory and protocol document storage (protocol, informed consent form, Investigator Brochure (IB), FDA IND/IDE approval letter as applicable).

B. Optional activities in OnCore™:

1. Protocol Calendar
2. Task Lists for key activities (ie. Activation, study close-out), Financials console
3. Subject tracking through calendar visits
4. Staff profiles and credentials
5. OnCore™/Forte Electronic Data Capture (EDC) Module
6. Auditing/Monitoring functions
7. Staff Effort Tracking

C. In relation to OnCore™, it is the Principal Investigator's, or delegated research team member's responsibility to:

1. Maintain an accurate delegated staff list
2. Approve the Protocol calendar and budget, if used, with the applicable signoffs
3. Invoice/reconcile payments
4. Use the demographic feed from EPIC appropriately when registering a subject
5. Ensure the subject statuses are up to date
6. Maintain regulatory documentation and approvals

D. Repeated noncompliance with this SOP may result in withdrawal of further research privileges by WVU/HSC Executive Leadership.

History of Revisions to SOP

Effective Date	Nature of Revision