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

STANDARD OPERATING PROCEDURE

Title:	No.: COE-108.00	
ClinicalTrials.gov Disclosure	Page 1 of 3	
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Prepared by:	Reviewed by:	Approved by:
09 APR 2021	09 APR 2021	17 APR 2021
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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 disclosure of clinical trials in Clinicaltrials.gov for Applicable Clinical Trials (ACT) according to the requirements of the Food and Drug Administration (FDA), Health and Human Services (HSS) regulations and the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information.

Scope:

This SOP applies to all Applicable Clinical Trials according to the following specifications:

- Food and Drug Administration Amendments Act (FDAAA) of 2007 as implemented by the HHS Final Rule
- NIH Policy (2017) for Clinical Trials Registration Requirement
- Qualifying trial which will render claims for items and services from the Centers for Medicare and Medicaid Services (CMS)

Clinical trials that are not applicable to the above policies should be considered for registration on Clinicaltrials.gov to comply with the International Committee of Medical Journal Editors (ICMJE) requirements for publication.

Materials:

Attachment 1- Guide for Timeline Requirements on ClinicalTrials.gov

Responsibility:

This SOP applies to all personnel involved in the conduct or supervision of clinical trials at the Health Sciences Campus of West Virginia University and for which the responsibility for ClinicalTrials.gov disclosure is with the Principal Investigator/West Virginia University (eg. Investigator-initiated clinical trials).

For clinical trials associated with an externally-held IND/IDE (eg. Industry study), the Sponsor is responsible for Clinicaltrials.gov registration. For trials sponsored or funded, even in part, by a federal agency the overall Principal Investigator (PI) should contact the Sponsor or agency to determine responsibilities.

Procedure:

A. Any West Virginia University Researcher, in the role of PI, who initiates or conducts an applicable investigator-initiated clinical trial, shall be designated as the Responsible Party (RP). The RP must ensure that registration, required record updates, and results reporting are completed and released in a timely manner.

B. The WVU IRB number will be used as the Protocol ID in the system. Applicable Clinical Trials must be registered in Clinicaltrials.gov prior to first participant enrollment.

C. Each WVU institution or department conducting Clinical Trials should appoint a ClinicalTrials.gov administrator to assist Investigators in establishing Protocol Registration and Results System (PRS) accounts for registration and management of protocols for which they are the designated RP. The West Virginia Clinical and Translational Science Institute (WVCTSI) Center of Excellence (COE) is available to provide guidance to PIs or other PRS users as needed throughout the disclosure process.

D. Registration must be done via the "WestVirginiaU" ClinicalTrials.gov PRS, unless the project receives external funding that is administered by another institution. The National Clinical Trial Identifier Number (NCT#) will be generated by the system once registration complete and can then be provided to WVU Financial Services or other institutional entities that require this number.

E. The WVCTSI Clinical Trials COE PRS Administrator or delegate will establish all user accounts for the PRS. Requests should be emailed to Ct.govAdmin@hsc.wvu.edu.

F. The WVCTSI COE will also periodically monitor the compliance status in the ClinicalTrials.gov WVU Registration system and report to the Director, WVCTSI who will escalate issues as needed.

G. Repeated noncompliance with this policy to register or submit results for applicable clinical trials can result in withdrawal of further research privileges by WVU/Health Science Center (HSC) Executive Leadership.

References:

1- FDAAA 801: Section 801 of the Food and Drug Administration Amendments Act of 2007 as implemented by 42 CFR Part 11: Final Rule
2- NIH Policy on Dissemination of NIH-Funded Clinical Trial Information
3- Centers for Medicare & Medicaid Services (CMS): CR 5790, Requirements for Including an 8-Digit Clinical Trial Number on Claims

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP

Timeline of Requirements for ClinicalTrials.gov Disclosure

1. A trial must be registered with the WVU IRB before it can be registered on ClinicalTrials.gov.
2. The trial must be registered on Clinicaltrials.gov no later than 21 days after the enrollment of the first participant.
3. Errors about the registration information for the trial must be corrected within 15 days.
4. The registration information must be updated within 30 days with a change to recruitment, status, overall recruitment status data elements and completion date.
5. The trial information must be updated at least every 12 months.
6. Informed consent must be posted to the website, after recruitment closes and no later than 60 days after the last participant study visit.
7. Results must be submitted in Clincialtrials.gov, no later than 12 months after the primary completion date.
8. Errors that are flagged in the results, must be corrected within 25 days after the date of notification.