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

STANDARD OPERATING PROCEDURE

Title:		No.: COE-104.00	
Registration of Clinical Trials		Page 1 of 3	
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Purpose:

This standard operating procedure (SOP) describes the procedures related to registration of Clinical Trials with the West Virginia Clinical and Translational Institute (WVCTSI) Clinical Trials Center of Excellence (COE).

Scope:

All clinical trials conducted by investigators of the Morgantown Health Science Campus (HSC) of West Virginia University and affiliated academic medical center must be registered with the WVCTSI Clinical Trials Center of Excellence. 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.

All human subject research meeting the NIH definition of a clinical trial must be registered with the WVCTSI Clinical Trials Center of Excellence.

If the answer is Yes to all of the following 4 questions, the study is a clinical trial and must be registered.

1- Does the study involve human participants?
2- Are the participants prospectively assigned to an intervention?
3- Is the study designed to evaluate the effect of the intervention on the participants?
4- Is the effect being evaluated a health-related biomedical or behavioral outcome?

Materials:

NA

Responsibility:
This SOP applies to all personnel involved in the conduct or supervision of human subject research at the WVU Morgantown HSC campus and affiliated academic medical center.

Procedure:

1. West Virginia University encourages and supports clinical trial-related activities performed in accordance with applicable regulations and policies.

2. Prior to enrolling any patients in a clinical trial, the Principal Investigator (PI) must register the trial with the WVCTSI Clinical Trials Center of Excellence. The PI must also obtain approval from the Institutional Review Board (IRB) as well as ensure there is an executed clinical trial agreement for studies where an external Sponsor is involved or an external entity is providing proprietary material.

3. The registration of a clinical trial will be via the WVU+kc system using the COE module at kc.wvu.edu. As a WVU IRB number is required to initiate COE registration, a WVU IRB protocol submission should be initiated prior to initiation of COE registration as there is a way to pull information from the IRB submission module . Registration should be performed when a study protocol and negotiated budget are final indicating the trial is likely to be initiated. Note, WVU IRB approval/acknowledgement is not required for COE registration and approval.

4. The registration will require a fee. It is expected the fee will be covered as follows:

    a. For industry (and possibly cooperative studies), the fee should be included in the trial budget and will be a pass-through cost to the sponsoring entity
    b. For federally-funded trials (eg. NIH), the fee will be covered by indirects
    c. For trials funded by WVCTSI pilot awards and for WVCTSI clinical scholars, WVCTSI will cover the fee
    d. For unfunded investigator-initiated/sponsored trials or for funded trials without indirect costs, the departments will cover the fee

5. A risk assessment will be performed based on the answers to COE registration questions and will determine whether a clinical trial is deemed low, minor, moderate or high risk to the institution. Refer to the SOP related to Clinical Trial Risk Assessment and Appeals Process for details.

6. For registered clinical trials, the following services will be included:
    a. Centralized resources, Standard Operating Procedures and templates
    b. Training and continuing education events for investigators and research personnel
    c. Internal quality audits for selected clinical trials and regulatory monitoring as required
    d. FDA or Sponsor audit readiness preparation and support
    e. Investigational New Drug(IND)/ Investigational Device Exemption (IDE) guidance
    f. Forte OnCore™ clinical trial management system support
    g. ClinicalTrials.gov disclosures support

7. For registered clinical trials, the following optional services may be requested (additional fees may be charged):
    a. Study coordination support such as recruitment, specimen collection, data entry
    b. Regulatory support such as IRB submissions, IND/IDE, trial master file maintenance
    c. Financial support such as budget negotiation, sponsor invoicing
    d. Investigational New Drug(IND)/ Investigational Device Exemption (IDE) development, submission and reporting

8. In the event the COE becomes aware a Principal Investigator fails to register a clinical trial, a notification letter will be sent requesting registration within 15 business days. If the trial has not been registered within 15 business days and the COE has received no communication, a second letter will be sent as notification, providing the PI 5 days to register otherwise WVU Health Science Center (HSC) Leadership will be notified.

9. Repeated noncompliance with this policy to register clinical trials with the COE can result in withdrawal of further research privileges by WVU/HSC Executive Leadership.

History of Revisions to SOP

Effective Date	Nature of Revision
16 Apr 2021	New SOP