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

STANDARD OPERATING PROCEDURE

Title:		No.: COE-119.00	
Clinical Trial Risk Assessment and Appeals Process		Page 1 of 3	
		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: 17 APR 2021 Sally L. Hodder, MD	

Purpose:

This standard operating procedure (SOP) describes the procedures related to the risk assessment and appeals process for Clinical Trials registered with the West Virginia Clinical and Translational Institute (WVCTSI) Clinical Trials Center of Excellence.

Scope:

All clinical trials conducted by investigators of the Morgantown Health Science Campus (HSC) and affiliated academic medical center sites in Morgantown must be registered with the WVCTSI Clinical Trials Center of Excellence and be approved following a risk assessment.

Materials:

Attachment 1- Risk Assessment

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 sites in Morgantown.

Procedure:

West Virginia University encourages and supports clinical trial-related activities performed in accordance with applicable regulations and policies. Before enrollment of any trial participants is initiated in any clinical trial conducted at the WVU Morgantown HSC campus and affiliated academic medical center in Morgantown, the following must be completed:

- The COE registration form (in the WVU +kc system) that includes risk assessment questions must be completed with PI approval. Note, the risk assessment questions and scoring were developed in association with WVU Health Science Center and WVU Medicine leadership.
- A one-time COE registration fee must be paid
- COE registration approval must be obtained

The following will be considered when determining whether to approve the University's participation in a clinical trial:

- The outcome of risk assessment from the clinical trial registration
- The roles of West Virginia University and of WVU Medicine/affiliated academic medical center
- The possible benefits to the participants, the larger community, and the University
- The proposed contractual agreements
- The research strategy of the University

A. Risk Assessment Process:

1. The risk assessment will calculate a total risk score based on the completed registration questions and will determine whether a clinical trial risk is deemed:
    a. low (risk score of 1)
    b. minor (risk score of 2)
    c. moderate (risk score of 3)
    d. high (risk scores ≥ 4, displayed as 4) to the institution.

The risk assessment questions can be found in Attachment 1.
In addition to the combination scores that total 4, clinical trials identified as 'first in human' or without indemnification for the trial and/or investigational product will automatically be identified as high risk (score of 4). Investigator-initiated trials that are more than minimal risk and for which the PI is responsible for the IND/IDE or for which there is no FDA approval for the investigational product or the approval is for a different indication will also be automatically identified as high risk (score of 4).

Clinical trials that are identified as having a risk of 4, 'first in human' or for which the PI is responsible for the IND/IDE will require that the PI (or at least one of the co-PIs) is a full-time faculty member or full-time employee of WVU.

2. The Risk Assessment Committee (RAC) will review clinical trials referred by the Clinical Trials Center of Excellence as well as all the trials identified as high risk.

    a. The committee will be comprised of:
        i. Associate Vice President, Clinical and Translational Science and Director, WVCTSI, WVU
        ii. Vice President of Clinical Programs, WVU School of Medicine
        iii. Assistant Vice President and Senior Clinical Operations Counsel for the West Virginia University Health System
        iv. Deputy General Counsel for Innovation and Research, WVU.
    b. The review will be completed within 10 working days, and the PI will be notified in writing of the decision (approval/denial with rationale for denial).
    c. The outcome of the RAC review is available to the Office of Sponsored Programs, as needed, to facilitate contract review.

B. Appeals Process:

1. If the study is not approved by the RAC, the PI can appeal the decision to the Appeals Committee. The appeal must be initiated within 30 days through the WVU+kc system. The Appeals Committee is comprised of the members of the Risk Assessment Committee as well as:
    a. The Vice President and Executive Dean for Health Sciences, WVU and Dean, School of Medicine
    b. Vice President and General Counsel, WVU Health System
    c. General Counsel, WVU.

2. During the appeals process, the PI will be given the opportunity to meet with the Appeals Committee in person to describe the value of the trial to the institution as well as any procedures to be implemented to mitigate the risks identified. The Appeals Committee will make a final determination and issue a letter to the PI. The outcome will be to approve or deny the clinical trial. The Appeals Committee decision is considered final and cannot be further appealed.

History of Revisions to SOP

Effective Date	Nature of Revision
17 MAY 2021	New SOP

Attachment 1: Risk Assessment

Questions to assess risks and associated risk scores:

Question	**Risk points**
Type of study: Industry-sponsored, Cooperative, Federally-funded Investigator-Initiated, Investigator-Initiated	 0 0 0 1
Is the trial greater than minimal risk?	1
Is there FDA approval for the investigational product?	2 if No
If yes, is the approval for the same indication?	2 if No
Is the study 'first in human'?	4
Is the investigator responsible for the IND/IDE?	2
Is there indemnification for the trial and/or the investigational product?	4 if No
For how many clinical trials has the Principal Investigator for this trial been the PI prior to this one?	≤3 adds 1