



West Virginia Clinical and Translational Science Institute
Clinical Trials Center of Excellence
STANDARD OPERATING PROCEDURE

Title: Mission, Goals and Governance	No.: COE-101.00	
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	Date of Issuance: 16 APR 2021	Date Effective: 17 MAY 2021
	Supersedes: NA	
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Purpose:

This standard operating procedure (SOP) describes the mission, goals and guidelines of governance for the West Virginia Clinical and Translational Science Institute (WVCTSI) Clinical Trials Center of Excellence (COE).

Scope:

This SOP applies to the conduct of all clinical studies conducted at WVU Health Science Center and affiliated academic medical center site on the Morgantown campus.

Materials:

NA

Responsibility:

It is the responsibility of the Director of the WVCTSI to approve all SOPs. The Director assumes ultimate accountability for all SOPs. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs.

Mission and structure:

The WVCTSI COE provides infrastructure that facilitates participant safety and regulatory compliance while providing efficiency that drives growth of cutting-edge clinical research at West Virginia University. All clinical trials conducted at the Morgantown Health Sciences Campus or affiliated health system must be COE registered and approved. The COE also facilitates use of regulatory systems for clinical trial conduct and management, allowing tracking of performance targets and metrics.

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- The Senior Executive Clinical Research Committee is comprised of university leadership and provides advice and guidance. This committee is routinely informed on the activities of the COE through the TAC and COE leadership and reviews any new or updated COE SOPs.
- The Risk Assessment Committee (RAC) is comprised of University leadership and legal representatives and review, as needed, clinical trials that are deemed of higher risk prior to COE registration approval being granted.
- The Clinical Trials Tactical Advisory Committee (TAC) is comprised of members from the COE as well as clinical research representatives across the university and establishes, promotes and maintains intuitional harmonized processes (SOPs) to facilitate human subject safety, ensure compliance to accepted regulatory requirements in clinical research and increases efficiency.
- The CTSI Clinical Trials (CTSI-CT) team resides within the COE/WVCTSI and provides the administrative, financial, business, coordination, data management, and regulatory infrastructure for investigators as needed. The purpose is to assist with the planning, conduct and compliance of clinical trials involving medications, devices or behavioral interventions, including those sponsored by private and public agencies. CTSI-CT coordinates and facilitates research and strives to ensure institutional research compliance (including financial compliance).

Goals:

- To facilitate the administrative, regulatory, financial and business activities necessary to assist investigators in the conduct of clinical research;
- To assist investigators who wish to offer novel, experimental therapeutic alternatives for the patients;
- To act as a resource for developing researchers with ideas, support, direction and opportunities related to protocol development and research funding;
- To assist in making WVU attractive to prospective research faculty and sponsors;
- To provide resources for clinical research compliance and education.

Governance:

The Clinical and Translational Science Institute COE functions to support the research activities of West Virginia University Health Sciences Center.

The COE follows guidelines outlined in:

- West Virginia University Administrative Policies and Procedures
- Departmental specific Policies and Procedures, as applicable
- West Virginia University Office of Research Integrity and Compliance

Additionally, the COE complies with applicable federal, state and local laws, rules and regulations.

History of Revisions to SOP

Effective Date	Nature of Revision
17 May 2021	New SOP