



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.22, Clinical Trial Budget Development

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to establish a standardized budget development process for clinical trials. This ensures financial accuracy, supports compliance with applicable federal regulations, and mitigates institutional and patient risk.

REVIEW: This HSCEP OP will be reviewed October 1 of each odd-numbered year by the associate director and senior director of the Office of Research (OR), with recommendations for revisions submitted to the vice president for research (VPR) or designee.

POLICY/PROCEDURE:

I. Introduction

Clinical trial budget development must be based on the approved Clinical Trial Coverage Analysis (CTCA) and incorporate institutional fee schedules and third-party service provider costs. The budget must align with the Clinical Trial Agreement (CTA) and the Informed Consent Form (ICF).

This OP governs budget development only. Billing and charge reconciliation are addressed separately under HSCEP OP 73.23 Clinical Trial Billing Compliance.

II. Applicability

- A. TTUHSC El Paso. This policy applies to all TTUHSC El Paso investigators/research staff, and personnel involved in clinical research financial operations, including coverage analysis, budget development, contract negotiation, and coordination with service providers.

III. Definitions

Clinical Research Finance (CRF): Unit within the Office of Research.

Clinical Trial Agreement (CTA): A legally binding contract between TTUHSC El Paso and the sponsor that outlines financial and operational obligations.

Clinical Trial Coverage Analysis (CTCA): A systematic review of all procedures, tests, and visits in a clinical trial protocol to determine which items are standard of care and which are research-only.

Informed Consent Form (ICF): A document that explains the purpose, procedures, potential risks, and benefits of a clinical trial to prospective participants. It is an educational tool and a legal record of the participant's voluntary agreement to participate in the study.

Third Party Service Providers: External providers (e.g., UMC, labs, imaging centers, pharmacies) contracted to deliver services for the clinical trial.

IV. Responsibilities of Investigators/Research Personnel

- A. TTUHSC El Paso investigators/research personnel shall have the following responsibilities with regard to developing a clinical trial.

Coverage Analysis. A Clinical Trial Coverage Analysis (CTCA) must be completed prior to budget development. Refer to HSCEP OP 73.21 Clinical Trial Coverage Analysis for All Clinical Trials, for detailed requirements.

Budget Development

- Clinical Research Finance (CRF) and the study team will prepare an internal budget incorporating institutional and service provider fees.
- The internal budget must be developed using the institutional budget template tool.
- Once finalized, the internal budget will be reconciled with the sponsor's proposal and transferred into the sponsor's required budget format.
- The internal budget must reflect all identified costs in the approved CTCA.

Budget Negotiation

- CRF or the department administrator, in collaboration with the Principal Investigator (PI), will negotiate with the sponsor.
- The final negotiated sponsor budget must not fall below the internally approved budget.

Document Harmonization

- The study team must ensure consistency between the CTCA, CTA, and, ICF.
- Study procedures, costs, billing designations, and subject injury language must align across all three documents.
- Discrepancies must be reconciled prior to approval and execution.

PI Approval. PI will certify the final internal and sponsor budget, acknowledging financial obligations and confirming consistency with the protocol, CTA, and ICF.

Documentation. The following documents must be maintained in the administrative file, and should be clearly dated and labeled to ensure version control.

- Final approved CTCA
- Internal and sponsor budget(s)
- Executed CTA
- ICF

Protocol Amendments. Any protocol amendment that alters study procedures or cost structure must trigger re-review and update of the documents listed in the Documentation section (CTCA, internal and sponsor budgets, CTA, and ICF if applicable).

V. Compliance

Compliance with this policy will be monitored by the Office of Research and is subject to audit.

VI. Amendments

TTUHSC El Paso reserves the right to modify, amend, or terminate this policy at any time.