



Contracts and Grants Accounting

Title: CLINICAL TRIAL FINANCIAL CLOSEOUT PROCEDURE	Related Operating Policy Number: 65.03, 65.10
Regulation Reference:	Effective Date: February 2016

Policy Statement:

It is the policy of Texas Tech University Health Sciences Center at El Paso (TTUHSC at El Paso) to manage clinical trials in a manner consistent with established accounting and research policies and procedures.

Scope and Distribution:

This policy applies to industry sponsored, investigator-initiated, and federal clinical trials operating on a fee-for-service basis. It does not apply to grants or other sponsored projects operating on a cost reimbursement basis.

Procedure:

Research personnel should review **OP 65.03 Sponsored Program Fund Management**, which specifies departmental fiscal management responsibilities during the conduct of a clinical trial. The following steps must be performed upon completion of a clinical research study (i.e., after final study visits for all patients and after the payment of all study related expenses to outside vendors):

1. The Principal Investigator and/or designee shall review the study’s financial status to assure that all invoices and payments due on the study have been paid.
2. The Principal Investigator and/or designee shall review transactions on the clinical trial fund to ensure that special augmentations are not paid from the restricted clinical trial fund.
3. The Principal Investigator and/or designee shall notify the Office of Sponsored Programs and Contracts and Grants Accounting (CGA) to proceed with closeout procedures for the specific study. CGA shall commence closeout procedures to assess compliance with the internal budget and with the sponsor-approved budget, and will determine the appropriateness of all revenue and expense transactions posted to project fund. The Principal Investigator and/or designee shall complete and submit a signed copy of the Clinical Trial Closeout Checklist and Certification Form.
4. CGA shall determine the final residual amount to be transferred to an unrestricted general designated account in the department of the Principal Investigator in accordance with OP 65.10. The department shall submit a budget revision in the budget revision system to transfer any final residual amount once notified by CGA.

Procedure Number: 65.03-01	Original Approval Date: 04/2014
Version Number: 2	Revision Date: 2/2016