

***Contracts and Grants Accounting***

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| Title: | **CLINICAL TRIAL FINANCIAL CLOSEOUT PROCEDURE** | Related Operating Policy Number: | **65.03** |
| Regulation Reference: |  | Effective Date: | **January 2016** |

# Policy Statement:

It is the policy of Texas Tech University Health Sciences Center El Paso (TTUHSC 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 department-level fiscal management responsibilities in the conduct of clinical trials. The following steps must be performed upon completion of a clinical research study (i.e., after final study visits for all patients and after payment of all study-related expenses to outside vendors):

1. The Principal Investigator (PI) and/or his/her designee shall review the study’s financial status to ensure that all invoices and payments for the study have been paid.
2. The PI and/or his/her 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 PI and/or his/her designee shall notify the Offices 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 sponsor-approved budget, and will determine the appropriateness of all revenue and expense transactions posted to project fund. The PI and/or his/her 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 PI in accordance with **OP 65.10, Residual Funds Derived from Drug Studies, Clinical Trials, Fixed-Price Contracts, and Investigator-Initiated Research**. The department shall submit a budget revision in the budget revision system to transfer any final residual amount once notified by CGA.

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| Procedure Number: | **65.03-01** | Original Approval Date: | **04/2014** |
| Version Number: | **2** | Revision Date: | **12/2015** |

**Texas Tech University Health Sciences Center El Paso**

# Clinical Trial Closeout Checklist and Certification

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| --- | --- | --- | --- |
| Principal Investigator: |  |  |  |
| Sponsor: |  |  |  |
| Study Title: |  |  |  |
| IRB Approval Number/Study Protocol Number: |  |  |  |
| Fund Organization Program (FOP): |  |  |  |
| Study Site: |  |  |  |
| Location of Study Records: |  |  |  |
| Number of Years Required for Record Retention: |  |  |  |

## The Principal Investigator is to complete this form and submit to the Office of Sponsored Programs and the Office of Contracts and Grants Accounting prior to closing a clinical trial account.

***Compliance Confirmation of Revenue and Expenses***

The Sponsor has been notified of all services performed; and all case report forms have been submitted; confidential information returned; and study drug and devices have been returned or destroyed, as appropriate.

Closure and conclusion of Internal Review Board (IRB) oversight has been confirmed (attach to form).

All revenue has been received and matches the expected payment amount based upon enrollment and patient completion of study (no outstanding payment due).

All appropriate personnel-related expenses have been charged to the project according to the clinical trial agreement, internal budget, and university policies and procedures.

An audit has been performed on all medical services to ensure that all study procedures have been charged correctly.

Ensure that no standard of care services were billed to the project unless approved in the original budget for all patients/subjects.

Ensure all study related services were billed appropriately to the project and not to third-party payers. All other direct expenses have been properly recorded on the project fund. No unrelated study costs have been charged to the project.

All encumbrances havebeencleared.

No outstanding payments are due to any other source, including a refund to sponsor.

For all projects with residual balances (income exceeding expenses) in excess of 25 percent, a letter is attached stating why the significant variance exists.

**Study Participants**

Number of subjects that participated in the study. Of the total, how many: Completed the study

Dropped out Screened failures

## I certify that the study has been completed according to the terms and conditions of the clinical trialagreement and accounting statements reflect all appropriate revenue andexpenses.

Principal Investigator Date Administrative Manager Date