

El Paso - Ambulatory Clinic Policy and Procedure

Title: STUDY CLOSEOUT PROCEDURES	Policy Number: EP 1.20
Regulation Reference:	Effective Date: 07/2014

Policy Statement:

It is the policy of Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) that clinical trials are managed in a manner consistent with established accounting, legal and funds flow policies.

Scope and Distribution:

This policy applies to fee for service contracts, industry sponsored or investigator initiated clinical trials. It does not apply to federal or state funded grants.

Procedure:

Research personnel should review OP 65.01 **Sponsored Program Fund** Management, which specifies Departmental fiscal management responsibilities during the conduct of a clinical trial. Upon completion of a research study, including final study visits for all patients, the payment of all study related expenses to outside vendors, but prior to any distribution of residual funds to a general designated fund.

1. The Principal Investigator will review the documents to assure all invoices and payments due on the study have been paid.
2. The Principal Investigator will review transactions on the clinical trials fund to ensure that special augmentations are not paid from the restricted clinical trials fund.
3. The study shall receive a close of study review conducted by the Business Affairs-El Paso. To initiate the review, the account manager of the restricted clinical trials fund shall contact Business Affairs-El Paso and gather the following items at a minimum:
 - a. Signed copy of the Clinical Trial Closeout Checklist and Certification form
 - b. The final approved itemized budget and routing sheet with approvals
 - c. Copies of invoices associated with all disbursements made from the restricted clinical trials fund
4. The department will submit a budget revision in the budget revision system to remove any remaining budget for IDC and transfer the remaining funds to the appropriate unrestricted general designated account. Signed copy of the Clinical Trial Closeout Checklist and Certification form should be included.

Policy Number:	Original Approval Date: 07/2014
Version Number: 1	Revision Date:
Signatory approval on file by: Michael J. Romano, M.D. Associate Dean of Clinical Affairs Clinic Operations Committee, Chair Texas Tech University Health Sciences Center at El Paso	