

Texas Tech University Health Sciences Center El Paso

Clinical Trial Closeout Checklist and Certification

Principal Investigator:	
Sponsor:	
Study Title:	
IRB Approval Number/Study Protocol Number:	
FOP:	
Study Site:	
Location of Study Records:	
Number of Years Required for Record Retention:	

PI 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 or devices have been returned or destroyed as appropriate.
- Confirmation of closure and conclusion of IRB oversight (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 3rd 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 have been cleared.
- 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%, a letter of explanation 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

Screen failures

I certify that the study has been completed according to the terms and conditions of the clinical trial agreement and accounting statements reflect all appropriate revenue and expenses.

Principal Investigator _____ Date _____

Administrative Manager _____ Date _____