

El Paso - Ambulatory Clinic Policy and Procedure

Title: BUDGET APPROVAL PROCESS FOR CLINICAL TRIALS	Policy Number: EP 1.19
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:

1. Each Department shall develop a list of individuals authorized to negotiate with pharma on costs of trials (note, these individuals are NOT authorized to negotiate any contractual language). The Associate Dean for Research is the only individual authorized to obligate TTUHSC El Paso for clinical trials. Each negotiated budget is subject to review and approval as defined in this policy.
2. Upon receipt of protocol package including protocol, the principal investigator (PI) shall develop a budget as defined in this document.
3. Each contract must include the following costs:
 - a. IRB initiation fee
 - b. IRB amendment / revision fee
 - c. Continuing review fee (minimum annually, but frequency determined by IRB)
 - d. Indirect cost %
 - e. Continuing review charge (minimum annually, but based upon IRB determined level of risk)
 - f. A detailed budget showing costs of required visits, documentation and testing by date, any proposed patient stipend, pharmacy and nursing costs, archive and FDA audit fees, and the corresponding sponsor payments. This shall include payments for physician visits in the budget.
4. The PI shall be responsible for submitting, as part of the approval process, a detailed budget for the project.
 - a. For protocols that are paid “per patient”, the budget shall be in a form which compares proposed payments to current Medicare reimbursement. The institution will not accept budgets which propose a “per patient” payment without detail of payment per service. In the event of payment disputes, the absence of such itemization makes it difficult to reconcile payments.
 - b. For protocols that involve a “percent effort” by individuals, the budget should include a breakdown of the salary support charged to the grant or contract, and the actual cost of the percent effort proposed including salary and benefits.

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- i. In the event that the grant / contract does not cover the full costs of an individual's percent effort, the routing sheet must indicate cost sharing and the appropriate Department account this will be charged to.

5. The PI shall provide a spreadsheet detailing all required services with a time line, and proposed sponsor payment and Medicare payment for the service. The current Medicare fee schedule may be obtained by reviewing Attachment A, How to Access the Medicare Fee Schedule. Use the Non-Facility Price. If any services are to be contracted, a column with actual contract payment shall be provided.

6. The routing of the proposed budget for approval shall be
 - a. PI
 - b. Department Chair(s)
 - c. Associate Dean for Clinical Affairs
 - d. Associate Dean for Research.

7. Final budget approval shall be as follows:
 - a. For contracts that include a "percent effort", the Associate Dean for Research
 - b. For contracts that are paid on a per patient basis, the Associate Dean for Clinical Affairs

8. Upon approval of the budget, the Associate Dean for Research will "marry" the budget with the approved contract language, execute the contract and forward to sponsor for signature. Upon return of a fully executed contract, the ADR will
 - a. Retain the original copy,
 - b. Forward a copy to the PI for safe keeping
 - c. Approve the budget in the budget revision system.

9. All agreements must be signed on or before the effective date of the agreement.

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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	