

El Paso - Ambulatory Clinic Policy and Procedure

Title: ROUTING AND STORAGE OF LEGAL DOCUMENTS RELATED TO CLINICAL TRIALS	Policy Number: EP 1.17
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. It includes all documents which, in some way, obligate the institution or its employees. It does not include those documents, such as informed consent documents, within the scope of the Institutional Review Board.

Procedure:

1. Each Department shall develop a list of individuals authorized to negotiate with industry sponsors 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.
2. Authorized individuals will route non-disclosure agreements (NDA's) and contract language (not including the budget) to the Office of Research in Lubbock.
3. The Departmental authorized individual communicates with Office of Research / Lubbock regarding required modifications to NDA's and contract language. OSP Lubbock will provide legal review of all clinical trial related contracts. Office of Research Lubbock does not review / approve the budgets associated with clinical trials.
4. Lubbock Office of Research will forward approved NDA's and contract language to the Associate Dean for Research, TTUHSC El Paso for execution.
 - a. NDA – The Associate Dean for Research (ADR) will execute the document and return to the sponsor. Upon receipt of fully executed NDA from sponsor, ADR maintains the original document and forwards a copy to primary investigator (PI).
 - b. For contract language including budget, the ADR will receive approved contract language from Office of Research, and will await routing / approval of budget as defined in the budgetary approval process for clinical trials. Upon receipt of approved budget, the ADR will execute the contract and forward it as well as the approved budget to sponsor for signature. Upon receipt of the returned document, the ADR
 - i. Maintains the original fully executed contract
 - ii. Forwards a copy of the fully executed contract to PI
5. The Department will enter a budget revision in the budget revision system to reflect approved budget and will add ADR as an additional approver. A signed copy of the approved budget will be added as an attachment.
 - a. Contract modifications are handled as in b. above. If the modification involves changes to a budget, the revised budget must be routed as defined in 5 above.

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Policy Number: EP 1.17	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 El Paso	