UTHealth
The University of Texas
Health Science Center at Houston

Sponsored Projects Administration

New Clinical Trials Checklist

This checklist provides guidance on the administrative process of initiating a clinical trial and the required documentation. Additional documentation may be necessary for each project. Consult with your assigned Contracts Specialist to determine if additional information is needed.

Negotiation/Internal Approvals

- ☐ Send draft Clinical Trial Agreement and sponsor contact information to your assigned specialist
  - Specialist assignments can be found here: http://go.uth.edu/PreAwardcontacts
  - Contracts Specialist will negotiate the terms of the CTA directly with the sponsor. Send these items to your Contracts Specialist upon receipt so that negotiations can begin as soon as possible
- ☐ Begin budget negotiation with sponsor
  - Department personnel will negotiate the budget directly with sponsor. Use the SPA Clinical Trial Budget template to develop your internal budget. The Clinical Trials Resource Center (www.uthouston.edu/ctrc) can assist with budget development if needed
  - Budget review/input may also be required by Memorial Hermann Hospital if study will be conducted on its premises
- ☐ Submit protocol and other required documentation to CPHS (http://www.uthouston.edu/cphs/) in order to initiate human subjects approvals
- ☐ Prepare Review & Approval Form (Review & Approval Form)
  - Ensure all fields are completed
  - Route for signature by Principal Investigator AND Department Chair or DMO
  - Send fully signed and completed Review & Approval form to Contracts specialist
- ☐ Forward Institutional Review Board approvals to Contracts specialist once approved
- ☐ Send finalized budget to Contracts specialist

Execution

Contracts Specialist will send contract to PI for "Read and Understood" concurrence or signature once all necessary documentation is received by Contracts (finalized contract, finalized budget, completed R&A). Contracts will then sign and send the partially executed contract to the Sponsor for signature.

NOTE: The agreement can be executed, but account cannot be setup without IRB approval.

Upon receipt of the fully executed contract and all applicable institutional approvals, Contracts Specialist will send the project to Post Award Finance for account setup. Departmental administrators will be copied on this correspondence.

Post Award Finance will notify the PI and department by email when account has been established.