

## **FREQUENTLY ASKED QUESTIONS**

### **Industry Supported Clinical Trials**

**Who may conduct clinical trials?** Only full-time UTSW faculty members.

**When should I contact the Clinical Trials Office (CTO)?** As soon as you know that you are going to participate in the study – prior Institutional Review Board approval of the study is not required for contract processing. The IRB and CTO work in parallel so that the investigator may have all legal and regulatory requirements approved in order to begin enrollment of study patients.

Also contact the CTO if you receive a confidentiality agreement related to review of a protocol for a clinical study *or* an amendment to an existing clinical trial agreement as institutional approval and signature are required.

**Is an agreement always required?** Yes, per UTSW policy.

**What does the CTO need from me?** An electronic version of the agreement, 3 hard copies of the protocol, 3 copies of the budget, eOGM-1 and Clinical Trial Worksheet forms completed through ERGO, and a signed copy of FDA Form 1572 (also known as “Application Materials”). The protocol may be double-sided in order to save resources.

**Can I sign the agreement myself?** No, an authorized UTSW official is required to sign all agreements. An agreement signed only by the investigator is not valid or enforceable.

**What is the overhead rate for the University?** 30%

**What is the IRB fee?** \$1500 for full board review, \$250 for expedited. If the Study is PI initiated (the PI is a UTSW employee), or financially supported by a state / federal / non-profit granting agency, no IRB fee is charged.

**What do I do if I receive a check for a clinical trial?** Please personally deliver it to the Clinical Trials Office, BPB.212. Please do not send to Accounting or the Office of Post Award Administration or thru campus interoffice mail.

**Will the contract specialist in the CTO put the budget together and negotiate the budget with the sponsor on my behalf?** No, that must be handled directly between the investigator and the sponsor.

**How do I put together a budget?** Review the protocol, determine the costs of the research procedures required, as well as pharmacy fees (monthly, dispensing), personnel costs, startup fees (from UTSW as well as Children’s, Parkland), etc., and compare to what funds the sponsor is offering. Also be aware that all clinical trial studies are subject to 30% overhead.

**How long will it take to complete an agreement?** There is no set answer. Many factors contribute to the time involved in negotiating the contract, such as the responsiveness of the sponsor, type of agreement, or whether a prior or master agreement exists. It is our policy to have all application materials (see above) in hand before negotiating the clinical trial agreement.

Please do not hesitate to call us at 214-648-6449 with any questions or concerns.