Clinical Trial Contracts Overview

CONTRACTS

It is important to keep in mind that contracts and grants are very different mechanisms of funding. Grants are *competitive applications* and contract are *negotiated offers*. Further, grant funds are awarded upfront and funds are drawn-down as expenses are incurred; however clinical trial awards work on a per patient reimbursement schedule.

There are two types of clinical trial (CT) protocols: *Sponsor-initiated and PI-initiated*

There are three types of CT funding: Industry, government, & philanthropic (or combinations thereof).

Sponsor-initiated are the most common. The sponsor writes the protocol and approaches PIs to participate. The sponsor "makes an offer" and the PI/Lurie Children's may "accept the offer as is" or "negotiate" for better terms.

There are approximately 9 steps to this process:

(1) Confidentiality Agreement is signed, usually between sponsor and PI, (but may also require Institution). The Confidentiality Agreement is essential to negotiate properly the terms of the agreement. **PIs are strongly encouraged to work with Kris Martens during this process.**

(2) Sponsor sends "Packet" to PI: Protocol, Investigator Brochure, ICF Templates, Clinical Trials Agreement (CTA) & Sponsor Budget. PI decides if they have the time, resources and staff to do the study.

(3) PI submits to IRB, but contemporaneously also forwards the CTA and Sponsor Budget to OSP to begin the negotiating process; include an internal budget (preferably) at this point. Please note that since sponsors use national averages for their "offer" and Lurie Children's is above the national average, the budget will almost always change over time.

(4) Negotiating the CTA: if there is a precedent document that can be used from a prior study, or there is a Master Agreement, if not, then the agreement will need to start from scratch.

(5) A checklist of contract terms is used to evaluate the contract as adequate for Lurie Children's standards. Many times there will need to be revisions to either ADD or REMOVE elements that are not in our favor/give too much advantage to the sponsor.

(6) Tracked changes of revisions are sent back to sponsor for Clinical Team to approve (if their legal has delegated that authority) or forward to the sponsor's legal department for review.

(7) While Contract is being reviewed, most sponsors have the Clinical Team negotiate the budgets (i.e. not the legal department).

(8) In theory and ideally: the IRB is reviewing the Protocol and the Contract and Budget are also under negotiation contemporaneously.

(9) Once the IRB approves the study: at that point if the Budget and Contract are satisfactory to all parties (Sponsor, PI, and Institution) then the final signatures may be obtained, and the study may begin.

PI-Initiated: usually the PI writes the protocol and approaches a sponsor for supply of study drug and/or funding. These are "Research Agreements" and require slightly different emphasis on certain terms to protect the PI/CMH interests. Budgets are also usually proposed by the PI and use an internal budget to make an "offer" to the sponsor in order to cover the costs (more like a grant in this regard).