How to Get Your
Clinical Trial Agreement Finalized Faster
Clinical Research Center Learn-At-Lunch Series
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Click below to link to presentation.
http://www.unmc.edu/media/spa/october_2011_learn_at_lunch_presentation_qas.pdf

Q: Does SPA screen sponsors for designations such as Corporate Integrity Agreements (CIA)?

A. No, SPA does not routinely screen sponsors to identify those who may be under the terms of a corporate integrity agreement with the federal government. We are, however, familiar with various indicators that may suggest a CIA may be in place with a sponsor, such as:

- SPA's receipt of written notice from either the sponsor or the AG regarding compliance with CIAs
- Insertion of new, not previously reviewed, contract text (e.g. UNMC must comply with Sponsor's Fraud & Abuse Policy)
- Changes in sponsor practices regarding budget negotiations (no or reduced up-front payments) and revised payment practices (e.g. payment made only for services performed, fair market value discussions for services, etc.)

Q: Is the department responsible for finding out whether a sponsor is under a CIA, and is there a definitive way to know whether a CIA exists?

A. The department is not responsible for determining whether a CIA exists but may find the information helpful. A CIA can impact the budgeting process and/or consistency with previous contracts.

The United States DHHS Office of Inspector General (OIG) website is the best resource for identifying a sponsor who is under a CIA and obtaining a copy of the agreement.

Q: Is there a point in the budget/contract negotiation process whereby UNMC should put a sponsor on notice as to UNMC's relationship with TNMC?

A. Earlier is better in that explaining the UNMC-TNMC relationship and providing the sponsor with appropriate assurances can take time. SPA has been charged to seek indemnification from study sponsors for TNMC's participation in clinical research studies. As such, SPA inserts text into the indemnification section of the pending contract covering "affiliated hospitals and clinics where the study is performed."
It is SPA’s experience that larger pharmas are less resistant to the inclusion of such clauses as they have more experience conducting large multi-site trials. Conversely, small and mid-sized pharmas tend to have more concerns as to how such relationships are structured and seek assurances from UNMC that TNMC personnel will comply with the terms of the pending clinical study contract.

Q: Should the department disclose to the sponsor upfront that affiliates are involved?
A. It is sufficient for SPA to advise the sponsor during the negotiation process and work out any issues or concerns they may have.

Q: Who or what determines whether or a master agreement is put in place?
A. Either the sponsor or UNMC can initiate set-up of a master agreement. If a PI would like to work with a particular sponsor and believes a master would be helpful, the department can ask SPA to initiate the process.

Q: If SPA sends a contract to the department for review and the department notices language that concerns them, should the concerns be brought to SPA’s attention?
A. The primary reason SPA asks the department to review a contract during negotiation is to provide logistical information rather than to review legal terms. However, questions from the department are always welcome, and in some cases PI involvement may be helpful.

For additional information, contact Sponsored Programs Administration at 9-7456.