Clinical trial agreements: Hidden risks of poorly negotiated CTAs

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Fact or fiction?

1. Clinical trial agreements (CTAs) are "take it or leave it" propositions, and health care providers have no bargaining power to request changes.
2. The relative risks associated with CTAs are low and not worth spending the time or money to negotiate.

Both of these statements are fiction. Even when dealing with a study sponsor that is a big pharmaceutical company or medical device manufacturer, there is nearly always room for negotiation, if you ask. Below, we have identified some common CTA provisions that should be reviewed carefully and negotiated to ensure that the health care provider's interests (and those of its patients who may become study subjects) are adequately protected.

Subject injury – The CTA should:

- Address who will pay for subject injuries caused by a subject's involvement in the clinical trial;
- Be reviewed to identify any carve-outs or exclusions that could create unexpected expenses for the health care provider or the subject; and

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- Specify the agreed-upon rate/fees the sponsor pays for medical care provided as a result of a subject injury.

Indemnification – The indemnification section of the CTA should be reviewed to:

- Determine what sponsors ask to be indemnified for;
- Identify what sponsors have excluded from their own indemnification obligations; and
- Ensure that the sponsor has agreed to indemnify for injuries to subjects that are a direct result of the protocol or drug/device being studied.

Privacy/confidentiality/future use of subject data – Human subject research presents a number of risks related to the privacy and confidentiality of subject data. Health care providers should ensure that the CTA:

- Includes adequate protection for the maintenance of the privacy and confidentiality of subjects who participate in the research study, including:
    - their identity and other identifying information
    - information about their medical condition(s)
    - what subject data may be used for and who the sponsor may share it with;
- Does not permit the sponsor (or anyone on the sponsor's behalf) to use/share any data, except as described in the informed consent, HIPAA authorization and CTA; and
- Spells out any permitted future uses of subject data (consistent with the informed consent and HIPAA authorization (as applicable)).

Budget – The budget in a CTA should be reviewed to ensure that it:

- Adequately covers the health care provider's expenses in participating in the study;
- Sufficiently spells out what costs are being paid by the sponsor, so the health care provider can determine what costs may be billed to a subject's insurance; and
- Is consistent with the fair market value for the services to be performed by the health care provider and otherwise complies with all applicable laws, including the federal Anti-Kickback Statute, since health care providers are potentially in a position to order, purchase, refer or recommend the purchase of other products the sponsor makes or sells.

Agreements with Contract Research Organizations (CROs) – Some sponsors of clinical trials use CROs to provide research services on a contract basis on the sponsor's behalf. When a sponsor contracts with a CRO, the CTA is often signed by the CRO rather than the sponsor under a power of attorney or a letter of authority, and the sponsor is a third-party beneficiary to the CTA. This means that the sponsor is able to sue to enforce obligations under the CTA even though not party to the agreement.

But because the sponsor is not a party to the CTA, the health care provider participating in the study cannot sue the sponsor. Health care providers should request a letter of indemnification from the sponsor so that:

- There is a direct relationship with the sponsor in connection with the study; and
- The health care provider has a way to enforce its rights against the sponsor.