ASCO Research Community Forum

CONTRACT NEGOTIATIONS FOR CLINICAL TRIALS

– AT A GLANCE –

BOTTOM LINE

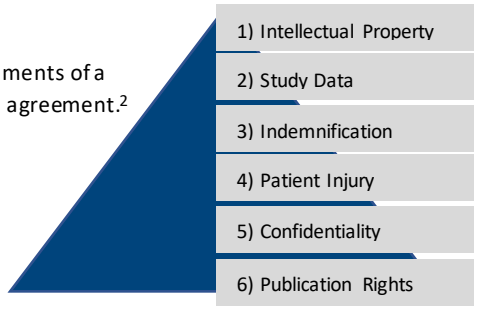
- Prepare for negotiations by reviewing relevant documents and familiarizing team members with process.
- Utilize strategies for effective communication.
- Use templates and template language for contract and budget negotiations.
- Consider joining online forums and meetings to share challenges and identify solutions with peers.

Negotiating clinical trial agreements is a routine and important activity for clinical trial sites conducting industry-sponsored research. Although all parties involved share the same goal of initiating trial enrollment, the contract must reflect their collective, and sometimes differing, needs, which can make the negotiation process complex and time-consuming.[1] Good clinical trial contracts help to ensure the sustainability of a trial site and guide how research will be conducted at the site.[2]

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES

The goal of contract negotiations is to ensure fair compensation to cover the work required for the protocol, facilitate enrollment targets with effective timelines, and establish long-term relationships between sites and sponsors. The most common pain points in the clinical trial agreement negotiation process are related to budget issues, process issues, legal issues, resource limitations, content barriers, and management barriers.[1]

Major elements of a clinical trial agreement.[2]



Preparing for Negotiations

Before beginning contract negotiations, consider the following best practices:

- ❑ Understanding all institutional policies for agreements, including: indemnification, subject injury and publication rights, research pricing (overhead rate and fair market value determinations), start-up costs, and project accounting.
- ❑ Thoroughly reading the entire protocol and all protocol documents (including consent) to ensure that the study can be properly conducted at the site and that appropriate (and sufficient) resources are available. Ensuring that the contract negotiator thoroughly understands the protocol requirements and consent document is critical.
- ❑ Conducting a thorough clinical trial insurance coverage analysis, which includes documentation to support billing, and identification of who is responsible for covering trial-related expenses. For more information on clinical trials insurance coverage, refer to the ASCO Insurance Coverage of Clinical Trials Toolkit available on asco.org/research-community-forum.
- ❑ Developing a thorough internal budget based on the coverage analysis and consent form wording. For more information on clinical trials budgeting, refer to the ASCO Insurance Coverage of Clinical Trials Toolkit available on asco.org/research-community-forum.
- ❑ Analyzing and understanding which site will be negotiating and with whom they will be negotiating; industry sponsor negotiations may be very different from Contract Research Organization negotiations.
- ❑ Determining parameters for ensuring negotiations and terms of agreement meet needs for site, and what to do if needs are not met.
- ❑ Ensuring subject injury language is drafted in accordance with national laws and regulations, such as Medicare.

Conducting Effective Negotiations

For effective communications and negotiations, consider the following best practices:

- ❑ Maintaining professionalism throughout the negotiation process.
- ❑ Determining a limit for email exchanges; a conference call may be more effective to discuss time-sensitive outstanding issues.
- ❑ Providing an agenda, backup documentation, and/or a compromise position in advance of teleconferences and meetings. Ensuring appropriate members of team are included, particularly in anticipation of contentious or complex content of the contract, can make negotiations more efficient.
- ❑ Knowing when to call for reinforcements and establishing when you cannot reach a deal that is satisfactory to both parties.
- ❑ Using a system to document all activities and communications, which can be helpful for evaluating workflow process improvement opportunities.

REFERENCES

1. Thompson MA, Hurley PA, Faller B, et al. Challenges With Research Contract Negotiations in Community-Based Cancer Research. *J Oncol Pract 12(6)*:e626-e632, 2016.
2. Baer AR, Hohneker JA, Stewart TL, et al. Negotiating for Success: Navigating the Contracting Process for an Exemplary Research Program. *J Oncol Pract* 6(2):107-110, 2010.

OTHER RESOURCES

- CEO Roundtable on Cancer and National Cancer Institute. Proposed Standardized/Harmonized Clauses for Clinical Trial Agreements. 2008.
- National Cancer Institute. Standard Terms of Agreement for Research Trial (START) Clauses - Informational Brochure. 2009.
- Clinical and Translational Science Award Work Group. Accelerated Clinical Trial Agreement (ACTA). 2014.
- First Clinical Research Model Agreements and Guidelines International (MAGI). MAGI Best Practice Standards.
- ASCO Research Community Forum Online Forum. Access: myconnection.asco.org/rcf.
- *American Society of Clinical Oncology Research Community Forum Toolkit: ASCO Clinical Trials Insurance Coverage Toolkit*. Alexandria, VA; American Society of Clinical Oncology; 2018.

Email researchcommunityforum@asco.org with ideas and suggestions for content revisions, additional and/or new topic summaries.

Visit asco.org/research-community-forum to learn more about the ASCO Research Community Forum initiatives and to access more resources and tools for oncology research sites.

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