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.\(^2\)

**Preparation 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

OTHER RESOURCES
• First Clinical Research Model Agreements and Guidelines International (MAGI). MAGI Best Practice Standards.

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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ACKNOWLEDGEMENTS
This document was developed with leadership from the ASCO Research Community Forum Resource Development Task Force. The following individuals made significant contributions to this document by providing insights, expertise, and resources, including Lora Black, RN, MPH (Chair of the Task Force); Elizabeth Blanchard, MD; Andrea Buchmeier, MHA, CCRC, LSSGB; Mehmet Sitki Copur, MD, FACP; Peg Ford; Marge Good, RN, MPH; Stephanie Graff, MD, FACP; Erika K. Radeke, MS; James A. Reeves, MD; Joel Saltzman, MD; Connie Szczepanek, RN, BSN, CCRP; Kelly Willenberg, DBA, MBA, BSN, CHRC, CHC, CCRP; and ASCO staff leads Patricia Hurley, MSc and Courtney Davis.

A Conquer Cancer Mission Endowment Award supported the development of this document.

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