Introduction

Negotiating a clinical trial agreement (CTA) can be a maze of confusion, filled with difficult-to-understand legalese and contractual traps seemingly around every corner. An accidental omission, an unintended commitment, or even just the wrong choice of words can lead to misunderstandings and an agreement that fails to do what you want it to.

This report shows how using the right words and phrases can make all the difference in successfully negotiating a CTA that will work for all parties. You'll learn the legal definitions of such terms as "confidential information," "hold harmless" and "indemnify," and how to properly use those terms in a CTA.

The report also will walk you through some of the most challenging – and most consequential – aspects of a CTA. Who should be a party to the agreement, and how should that be reflected in the preamble and recitals? Should the obligations protecting confidential information be imposed unilaterally or bilaterally, and what exceptions will you need to carve out to ensure that confidentiality protections don't interfere with the conduct of the study or your ability to comply with applicable laws? What obligations does each party have when it comes to preventing the participation of debarred or excluded individuals? And how can you construct indemnification provisions that protect the appropriate parties while not leaving anyone unnecessarily exposed?

Although non-lawyers often have an aversion to contract language and "legalese," it's worth learning to read, understand and effectively negotiate a CTA. When you understand the key words and phrases, you'll be much more likely to wind up with an agreement that protects all parties involved in the study.

About the Author

Eric Babineaux is the Lead, Legal Counsel at Clintrax Global where he leads a team of attorneys responsible for developing and implementing clinical trial agreements globally for pharmaceutical and biotechnology companies as well as CROs. Eric has more than six years of industry experience leading the negotiation of clinical trial agreements globally. During this time, Eric has assisted clients in the drafting of global contract templates and the creation of country-specific fallback while providing internal and external guidance to team members on legal issues arising in the negotiation process.