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Clinical trial agreements: Important or just one more document?

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Abstract

A review of the current literature suggests that the clinical trial agreement (CTA) may be a problematic area for clinical trial investigators. Some experts in the field believe this document is critically important to the study investigate, yet is one of the least understood study documents, rarely reviewed by investigators, and is often signed without reviewing the content. This key document governs the investigator's conduct of the study, as does the protocol, investigator brochure, and informed consent. While experts claim this is a problematic area rife for potential conflict between sponsor and investigator that could have serious legal ramifications little or no scientific data to support this belief was found in the literature reviewed. Using social and behavioral methodologies a survey was constructed to collect data on the factors influence investigators' knowledge, attitudes and perceptions about the CTA. Questions were framed to include all spheres of the Social Ecological Model and to analyze perceptions, beliefs and knowledge as outlined in the Health Belief Modal. Surveys were sent to investigators throughout the US, in various clinical trial environments, regions, and organization type. The data collected will help to establish current practices and provide guidance for possible future interventions and additional research. This will be the first public presentation of the data collected to truly determine whether this is a problematic area and if so how severe is the problem.

Biography

JoAnn Pfeiffer is completing her Doctorate of Science, in Regulatory Science at the University of Southern California. She holds Masters' Degrees in Regulatory Science and Public Health. She has directed clinical trials, served as compliance officer, and a subject matter expert in regulatory affairs. As part of the requirement for her Doctorate she conducted a systematic evaluation and analysis of the investigator's relationship to the clinical trial agreement. She will receive her Doctorate in December 2013 and is currently working as a consultant and a contractor in the biotechnology and pharmaceutical fields.