JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 11, No. 8, August 2015 "Happy Trials to You"

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

209. Have I got a deal for you!

In the informed consent process, we attempt to provide all the information that might be significant to a study participant. When the person asks a question, we clarify or expand on the information, but we do not change the informed consent form. In contrast, when a study sponsor gives an investigative site a clinical trial agreement (CTA), it is usually the *starting position* in a negotiation process. In other words, the document typically *improves*, from the site's perspective. The most sophisticated sites get the best terms (assuming performance records are comparable). Why is does the principle *caveat venditor* apply? Why shouldn't all comparable sites get the same terms? While regulations set ethical standards for informed consent, they don't do the same for CTAs, but does that mean the ethical standards should be lower? What am I missing here?

Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to ngoldfarb@firstclinical.com.

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.