

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

131. Trust me, I'm an expert

FDA Form 1572: Statement of Investigator requires principal investigators to attach a curriculum vitae or other statement of qualifications demonstrating that they are "expert in clinical investigation of the drug for use under investigation." In most studies, only a fraction of investigators are experts in clinical research. Of those, only a fraction are experts in the study drug, especially if it is not on the market yet. Nevertheless, every year, tens of thousands of investigators expose themselves to criminal penalties by making willful false statements to the FDA. If the FDA is not going to enforce this provision of the 1572, why force investigators to compromise their integrity with obviously false statements? Why not dial down the statement from "expert" to "competent" or even "not incompetent"? Then the FDA can actually enforce the commitment. 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.

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