

**What Am I Missing Here?**

**Thought-Provoking Questions for the Clinical Research Industry**

**By Norman M. Goldfarb**

**191. You told the FDA???**

I have heard of two instances in which investigators discovered study coordinator fraud. The investigators fired the miscreants, initiated thorough corrective action, and reported the problem to the FDA. Did the FDA thank the investigators for their honesty and good intentions? Not hardly. The FDA punished them with disqualification proceedings. Since study coordinators don't sign 1572s, the miscreants went unpunished, quite possibly to other sites, to continue their mischief. I have not heard the FDA's side of the story, but it should publish a clear statement that self-reporting will yield some leniency. 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](mailto:ngoldfarb@firstclinical.com).**

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