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Vol. 3, No. 9, September 2007 "Can You Handle the Truth?"

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

112. Why? Why not?

Once a potential study subject signs an informed consent form, it's on to the screening visit. Who cares why they signed up? If he or she doesn't sign up, who cares why not? They're history. But wouldn't it be useful to know why potential study subjects do or do not participate? Perhaps there is something about the study that you are not communicating clearly. Perhaps you are overstating the risks or the time required. Perhaps the informed consent form is incomprehensible. Perhaps your enthusiasm, or lack thereof, makes the difference. Wouldn't it be interesting to collect the reasons and look for patterns? A quick anonymous survey will probably generate very revealing information. What am I missing here?

113. Record retention

It is essential that sites store study records for at least a few years after a study. Of course, they should be stored safely, securely and accessibly. I recently visited a busy research site and asked to see their long-term records storage facility. I was the first outside person to ever see the room. If long-term records storage is so important, why not visit the room on the site qualification tour? What am I missing here?

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

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