Your Insurance Policy and Standards for Forms and SOPs

Thought-Provoking Questions for the Clinical Research Industry

Norman M. Goldfarb

Here are more puzzling practices, plus feedback from ACRP members:

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Do you know where your insurance policy is today?

Most sponsors cover the cost of treating study-related subject injuries that the subject's medical insurance does not cover. However, reimbursement by the subject's insurance company may impact the subject's coverage cap, assignment to a high-cost plan, or insurability. For example, a study drug may damage a subject's heart. If the subject then loses his job, he may be unable to obtain affordable insurance coverage. These risks need to be explained in informed consent forms (scary), worked out with the subjects' insurance companies (impractical), or assumed by the sponsor (uncertain). Alternatively, sponsors (or, better yet, a group of sponsors) could buy study-related injury insurance for all of the subjects, at least for low-risk studies. Companies in other industries band together to buy employee medical insurance. The cost of giving subjects a fair deal should be minimal. What am I missing here?

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And now for something entirely different

Considering how many laws and regulations constrain our industry, it is astonishing how little commonality there is between forms from one IRB to another. And I'm not even talking about local IRBs. We manage with a single 1572 form. Why can't central IRBs agree on standard forms for site submissions, adverse event reporting, protocol deviation reporting, etc? If an IRB wants an extra piece of information, it can tack that question on at the end. Study coordinators then wouldn't have to reinvent the wheel for every study. What am I missing here?

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No good deed goes unpunished

Everyone agrees that standard operating procedures (SOPs) help ensure consistent, high-quality research and compliance with laws and regulations. The more detailed the SOPs, the more consistent the quality. This is a good thing. But FDA 483 deviations are much more likely for sites that have comprehensive, detailed SOPs. Why? Because as SOPs become more comprehensive and more detailed, it becomes more and more likely that deviations will occur. Even though overall quality may close in on perfection, it is unlikely to reach 100%, and there can be exceptions that the SOPs did not anticipate. Why not limit SOP inspections to a more reasonable standard, and give sites credit for attempting to reach perfection? What am I missing here?

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Not that bloody in tooth and claw

There may be a place for ruthless competition, but the investigative site industry is not it. A homebuilder has to convince the customer that it is the one and only best choice. In contrast, an investigative site has to convince the sponsor that it is one of say, 50 sites that can do an acceptable job. That's sissy competition. Given all the common challenges that investigative sites face, more cooperation is in order. Let's work together to solve common problems, including some described in these columns. What am I missing here?

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Additional feedback and all previous *Monitor* issues are on the ACRP member only Web site. Log in at www.acrpnet.org. Please keep your feedback coming about any item in this column or any previous column. Simply send an e-mail to the author at ngoldfarb@firstclinical. com or editor@acrpnet.org.

ACRP Members Talk Back

M.W. responded to Item 1 (If we care so much about the welfare of the subjects, why don't we give them a voice in the process?):

"The informed consent process should include a review of who the subject can contact for information and complaints."

Good idea. A lot of subjects probably don't read all the way to the bottom of the informed consent form, where this information is usually found. Verbally reviewing this information will increase the consenter's credibility as well.

M.W. responded to Item 6 (If a subject has a problem, who is she supposed to talk to?):

"Unhappy patients talk to the office manager, phlebotomist, receptionist, etc. Sites need to train their staff to pass along complaints to the proper person, who is not necessarily the person who the complaint is about."

Carson Reider, a Research Subject Advocate at The Ohio State University, also responded:

"The NIH/National Center for Research Resources employs at least one Research Subject Advocate (RSA) at 90% of its 79 General Clinical Research Centers (GCRCs)." For more information, visit http://www.ncrr.nih.gov/clinical/rsa.pdf or contact Carson at reider-1@medctr.osu.edu.

Businesses with good customer service see complaints as opportunities to improve customer satisfaction. Kudos to GCRC! Who else has subject advocates? How is it working?

D.R. responded to Item 12 (Can I have fries with that burger, doctor):

"For the most part, foreign MDs are well-trained, intelligent and ambitious, but we had an unfortunate situation with one foreign MD who, due to his training, took on more than his authorized responsibility in evaluating adverse events and physical findings instead of collecting data and having the Investigator evaluate. He may have felt, because of his training and knowledge, that reporting 'sinus congestion' to the investigator for evaluation was beneath him. He also had a tendency to offer medical advice unrelated to the research study being conducted. As with some RNs and licensed physicians, who are new investigators, he did not always differentiate between clinical practice and clinical research practice."

Do some sites want RN and foreign MD coordinators to perform these functions? It would certainly relieve the Investigator of some work, although not the responsibility.

M.W. responded to last issue's Item 21 (Is it a big secret that investigators often conduct multiple studies?):

"It shouldn't be a secret to sites that sponsors, project managers, and monitors have multiple sites too."

Last year, we had a regional monitor assigned to over 20 different protocols. He didn't last long.

R.S. writes that her management has set forth a single metric for measuring coordinator performance: 100% enrollment in every study.

"While this is an admirable goal, it hardly reflects all the things to take into consideration, like patient welfare, for example."

So true. I'm convinced there is a specialized consultant who all the sponsors hire to slip in that subtle eligibility criterion that makes subject recruitment such a "challenge." Unless you only do one study, and do it over and over again, accurate projection of enrollment is virtually impossible. The U.S. Constitution guarantees every citizen the right to not read study ads, miss visits, and change their minds at the drop of a hat. It's no accident that enrollment problems delay 94% of studies.

M.B. asks why sponsors don't compensate sites for processing safety reports.

"In one current study, we have processed more than 300 in two years! Every one has to be read, understood, copied and reported to our IRB."

Sponsors usually submit safety reports to central IRBs, but we recently filled two big binders with reports for one study, mostly from parallel studies. Why isn't there a central Web site where sponsors can post safety reports and email alerts to IRBs?