From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, November 21, 2006 4:08 PM
To: [Redacted]
Subject: RE: greetings Ms. Carolyn

Dear [Redacted],

I'm sorry that it has taken me so long to get back to you--your e-mail got buried in the stack. My apologies.

In answer to your question, FDA's regulations do not prohibit a trial monitor from contacting trial subjects. I don't expect, however, that this is very common. I've heard of it mostly in instances where the sponsor suspected misconduct on the part of the clinical investigator and wanted to verify that specific subjects were indeed real, but I suppose it could be done in other situations as well. Nevertheless, there are some drawbacks/special concerns that you might want to consider before doing so, particularly before doing so on a routine basis.

One of the main drawbacks would be related to issues of confidentiality. 21 CFR 50.25(a)(5) requires that the consent form contain a statement "...describing the extent, if any, to which confidentiality of records identifying the subject will be maintained..." [See 21 CFR 50.25(a)((5).] FDA's regulations do not, however, have any specific requirements for sponsors, clinical investigators, or others, related to maintaining the confidentiality of records, and it would be important for the subjects to know what procedures the sponsor, clinical investigator, or monitor would put in place to protect the subjects' information. Also, the Health Insurance Portability and Accountability Act (HIPAA) would have a bearing on the confidentiality issue. That law is administered/enforced by the Office for Civil Rights, and thus, I would direct you to OCR's website (http://www.hhs.gov/ocr/hipaa/) for more information about OCR's regulations pertaining to maintaining the confidentiality of subjects' medical and other records under HIPAA.

Another drawback would be related to the potential for a monitor to influence study results or introduce bias into a study. Monitors may have information about the trial (that would not be available to the clinical investigator). Bias could be introduced, for example, if the monitor were to influence the clinical investigator with respect to inclusion/exclusion of one or more subjects, or if the monitor were somehow participating in collection of data, rather than carrying out their customary role (i.e., verifying how the site is carrying out specific trial activities and checking the accuracy of information that had already been collected).

I would also strongly urge you to consult with the Institutional Review Board or ethics committee that reviewed and approved the study to find out if the IRB would object to such contact. [IRBs, in particular, would be very interested in problems that you may have observed with respect to how the consent process is carried out.]

I hope this is helpful to you, and again, apologize for the slow response.

Carolyn

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From: [Redacted]
Sent: Friday, October 13, 2006 12:16 PM
To: Hommel, Carolyn - OC
Subject: greetings Ms. Carolyn

Hi Ms. Carolyn

[Redacted]

Hopefully I have a fairly simple question, this time. In a complex trial for which I am consulting, I have recently been doing a lot of site training visits, often with naive to research sites. I have, on occasions, in a teaching mode, interacted with potential patients-subjects. Mostly teaching the PI or coordinator, how to conduct a consent process properly. Of course, I have never had physical contact with a patient. I have been criticized by some peers, stating a "monitor may never interact with a patient". This, I take umbrage with. I reviewed FDA and GCP regulations again. I find a solid base of support to me, indicating that a thorough monitor may well, in specific scenarios, need to have interaction with a patient.

I am curious. Is there a specific written or anecdotal belief that a monitor may not see and or interact with patients in a trial being monitored?

Thanks, as always, MS. Carolyn.

[Redacted]