From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, June 08, 2006 7:39 AM
To: [Redacted]
Subject: RE: question

Dear [Redacted]:

Your questions to the GCP Questions e-mail account were forwarded to me for a response.

In answer to your first question, FDA's regulations do not prohibit a trial monitor from contacting trial subjects. Whether such contact would be a breach of confidentiality is beyond the scope of FDA's regulations. The only passage in the regulations (that I'm aware of) that addresses confidentiality is found in 21 CFR 50.25(a)(5), which 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).] The regulations do not, however, have any specific requirements for sponsors, clinical investigators, or others, related to maintaining the confidentiality of records. Perhaps you could consult with the Ethics Committee that reviewed and approved the study for more guidance about your concerns?

In answer to your second question, a "*legally acceptable representative*" is defined in section 1.37 of the ICH E6, "Good Clinical Practice: Consolidated Guidance," as "An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial." In other words, a *legally acceptable representative* is necessary when a subject is not mentally competent to make decisions for him- or herself. In the United States, the more commonly used term is "legally ***authorized*** representative." Appointment of a legally authorized representative for a mentally incompetent person is governed by applicable state law.

I need to point out that being illiterate--that is, being someone who cannot read and write--is not the same as being incompetent to make decisions. In the United States, a person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law. I refer you to FDA's Information Sheet Guidances for more information on the consent process. Here is a specific link to the portion of the Information Sheet on Informed Consent, dealing with illiterate subjects: http://www.fda.gov/oc/ohrt/irbs/informedconsent.html#illiterate . All of them can be viewed on FDA's Good Clinical Practice website: http://www.fda.gov/oc/ohrt/irbs/default.htm.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Tuesday, May 23, 2006 5:08 AM
To: OC GCP Questions
Subject: question

Dear Sir/Mam

1. Can a monitor contact the trial subject telephonically in a situation when a clinical trial monitor is suspecting a fraud at the investigator's site with prior permission of the sponsor. Is it a breach of subject's confidentiality.
2. Can a neighbor or a friend serve as legally acceptable representative in case of illiterate subject.

Regards
[Redacted]