From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, September 15, 2003 2:16 PM
To: [Redacted]
Cc: Lepay, David
Subject: RE: clinical trials

Dear Ms. [Redacted]:

Your proposal to document study participation in a patient/subject's progress notes seems reasonable to me. Because FDA regulations do not specify *how* the case history should be documented--only that it must be done--sites have flexibility regarding how best to carry this out.

I have a concern, however, raised by your description of what you would put in the progress notes, i.e., that you would annotate the progress notes to indicate that "Patient denies further questions at this time." You said that you might include this statement on a rubber stamp for the convenience of staff members to use in annotating the patients'/subjects' records. If a patient/subject had questions, how would this be documented using the rubber stamp that you describe? My concern is that including such a statement might discourage or stifle discussion about the study. You might wish to consider generally how you would like the records to be annotated (e.g., if the patient/subject has questions or does not, what the questions are), and train your staff to maintain the records accordingly.

You also asked if you were correct in thinking that "documenting in the chart IS NOT breaking confidentiality as to the patient becoming a study participant because the chart is a confidential document to begin with." I'm not sure I understand the question. Perhaps the following question and answer from FDA's Information Sheets for IRBs and Clinical Investigators addresses the issue:

> **38. The informed consent regulations [21 CFR 50.25 (a)(5)] require the consent document to include a statement that notes the possibility that FDA may inspect the records. Is this statement a waiver of the subject's legal right to privacy?**
>
> No. FDA does not require any subject to "waive" a legal right. Rather, FDA requires that subjects be informed that complete privacy does not apply in the context of research involving FDA regulated products. Under the authority of the Federal Food, Drug, and Cosmetic Act, FDA may inspect and copy clinical records to verify information submitted by a sponsor. FDA generally will not copy a subject's name during the inspection unless a more detailed study of the case is required or there is reason to believe that the records do not represent the actual cases studied or results obtained.

The consent document should not state or imply that FDA needs clearance or permission from the clinical investigator, the subject or the IRB for such access. When clinical investigators conduct studies for submission to FDA, they agree to allow FDA access to the study records, as outlined in 21 CFR 312.68 and 812.145. Informed consent documents should make it clear that, by participating in research, the subject's records automatically become part of the research database. Subjects do not have the option to keep their records from being audited/reviewed by FDA.

When an individually identifiable medical record (usually kept by the clinical investigator, not by the IRB) is copied and reviewed by the Agency, proper confidentiality procedures are followed within FDA. Consistent with laws relating to public disclosure of information and the law enforcement responsibilities of the Agency, however, absolute confidentiality cannot be guaranteed.

You may view all of FDA's Information Sheets on line by pasting the following URL into your browser: 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
Office of the Commissioner
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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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, September 02, 2003 1:29 PM
To: 'OC GCP Questions'
Subject: RE: clinical trials

Ms. Hommel

Thank you so much for your information. It is clear that you truly took the time to answer all of my questions in great detail.

I am just looking for more clarification regarding documenting in the progress notes. Can I specifically write, "Pt has been informed regarding "XYZ" study. Pt has agreed to become a subject/participant and has signed consent. Pt. denies further questions at this time. [Redacted] "

I have included the exerpt that you sent me stating.....

In 21 CFR 312.62(b), FDA's regulations for investigator recordkeeping and record retention, it states, "An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigaitonal dug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study."

It sounds to me like documenting in the chart IS NOT breaking confidentiality as to the patient becoming a study participant because the chart is a confidential document to begin with. Am I correct?

To take this one step further.....can I have a stamp made stating the above comments by the person obtaining consent, educated the staff, and then have them stamp the progress notes and then sign. I am thinking this might make compliancy much better and consistent. We have several surgeons in our department.

Thank you again for your time.

[Redacted]