From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, April 20, 2005 9:15 AM
To: [redacted]
Subject: RE: Computerized Systems Used in Clinical Trials

Dear [redacted],

Thank you for this and your April 8 inquiry about the very important issue on the extent to which electronic records/computerized systems used in clinical trials need to be Part 11 compliant. This same question was included in the comments submitted to FDA public docket established for the draft guidance entitled "Computerized Systems Used in Clinical Trials". These comments suggested that in order for information submitted in FDA submissions to be reliable, all computerized systems used to capture clinical trial information be Part 11 compliant. As you can imagine, this is a very compelling argument that supports the use of Part 11 controls for all computerized systems used to capture clinical trial information. As we move towards finalizing this guidance document, we will address this issue and include suggestions in the guidance about this issue.

In the meantime, I suggest that controls be utilized that help to ensure that all records (both paper and electronic) associated with clinical trials are accurate, complete, authentic, legible, reliable and trustworthy.

I'm sorry I cannot be more helpful here. If you have any questions, please feel free to contact me directly at 301-827-6473.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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: Thursday, April 14, 2005 4:27 PM
To: [redacted]
Subject: Computerized Systems Used in Clinical Trials

Ms. Beers Block,

I noticed that you are the contacted person listed for those with questions regarding the September 2004 Draft Guidance for Industry - Computerized Systems Used in Clinical Trials. I have a question that I hope you can either answer, or else forward to someone else who would be able to provide me with a response.

[redacted] medical staff is a clinical investigator in a multi-site IND research study. A small number of patients of the hospital are enrolled in the study. Hospital medical records are part of the "case histories" for these patients. These medical records are created and/or maintained in electronic form.

This particular investigator was contacted by the contract research organization ("CRO") for this IND study and asked to certify whether or not the site's computer systems are compliant with the electronic records and signatures regulations set forth at 21 C.F.R. Part 11. The [redacted] management information systems vendors, in turn, were asked by [redacted] to certify whether their systems were compliant. The medical records imaging vendor is in the process of installing a new version of their software and is willing to certify that the new software is compliance with Part 11. The [redacted] other large MIS vendor, however, is unwilling to do so, leaving it [redacted] to determine if the system is compliant.

All this begs the question, though, "Does the [redacted] computerized medical records need to comply with Part 11 because some patients are enrolled in an IND research study?" I believe the answer is yes, but I would appreciate some guidance nonetheless, because if the answer is really no, then a whole lot of work can be averted.

Additionally, I have a question about the following sentence from the September 2004 Draft Guidance, "If a computerized system being used for a clinical research study is part of a system normally used for other purposes, we recommend that efforts be made to ensure that the study software be logically and physically isolated as necessary to preclude unintended interaction with nonstudy software." Does this mean that the FDA wants medical records of patients enrolled in studies be kept on a separate computer system from other patients who are not so enrolled? I would think that would be impossible in the setting [redacted] where a small percentage of patients are enrolled in a study. Your guidance on this issue would be appreciated.

Thank you for your time. I look forward to hearing from you.

[redacted]