From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, December 16, 2005 2:41 PM
To: [redacted]
Subject: RE: Storage of Research Records

Dear [redacted],

Thank you for your inquiry. The best guidances available at this time that explain FDA's opinions on the use of electronic records and computerized systems used in clinical trials include "Guidance for Industry: Part 11 Electronic Records and Electronic Signatures Scope and Application Guidance" (http://www.fda.gov/oc/gcp/guidance.html; see 16th posting) and the draft "Guidance for Industry Computerized Systems Used in Clinical Trials" (http://www.fda.gov/oc/gcp/guidance.html; see 5th posting). As you familiarize yourself with these guidances you will see that it is FDA's opinion that It is permissible to transfer the content of information contained on paper records to electronic formats (such as pdf, xml, sgml files) and to archive this information on available media (such as CDs, floppy discs, etc.).

If you intend for these copies to substitute for the paper copies (i.e. destroy or dispose of the originals) then 21 CFR 11 applies http://www.fda.gov/ora/compliance_ref/part11/frs/background/11cfr-fr.htm. This regulation covers the use of electronic records and signatures used to meet an FDA record-keeping requirement. If you propose to maintain electronic copies of study records in lieu of the paper copy, your system for doing so would have to comply with the requirements of Part 11. For example, your process for copying and retrieval would have to meet expectations for availability and being able to generate electronic copies suitable for FDA review and further copying. There are a couple of points to consider. First, Part 11 applies only to the records that are required to be maintained by regulations. For clinical trials in general, sponsor record keeping and retention requirements are found in 21 CFR 312.57 and clinical investigator record keeping requirements are found in 21 CFR 312.62. Second, please note that retention periods are specified in the regulations. Records only have to be retained for the period of time indicated. You are free to decide how records are to be copied, stored or otherwise disposed of, if the records you propose to copy and archive are no longer required by FDA to be retained. That said, you do not have to keep the paper copies if your electronic system complies with Part 11. If you are unsure if you can comply with Part 11, it would be wise to retain the paper records as you suggest.

To meet regulatory requirements, records relating to the conduct of a clinical trial need to contain all of the information that was contained on the original records. If patient information and sponsor information were on the original research records, this information must be preserved. Your comment that sponsor information and patient information needs to be removed is incorrect. FDA needs to be able to review "complete and accurate" records maintained at the clinical site; these records should not be altered in any way when converted from paper to electronic media. I would direct your attention to the definitions of "certified copy" and "source documents" found in the Computerized Systems Used in Clinical Trials guidance for guidance on how one might successfully convert paper records to electronic records. You also may be interested in section 8 of the Consolidated Guide for Good Clinical Practice, which gives guidance on what records should be retained and by whom http://www.fda.gov/cder/guidance/959fnl.pdf.

I hope this information is helpful.

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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: Thursday, December 08, 2005 11:23 AM
To: gcpquestions@oc.fda.gov
Subject: Storage of Research Records

I would like to know if you could provide any guidance on the storage and retention of records. I understand the time commitments explained in 21 CFR 312.62, but I do not see any clarification that records must be maintained in paper format. I have read "original documents must be maintained" in other references, which would indicate paper records, if they were the original source of data capture.

I am seeking clarification because [redacted] is transitioning from paper medical records to electronic records. At this point, medical charts(not research records) are maintained in paper format until a patient is discharged, and then they are scanned into electronic format. From that point the original documents are destroyed, and the only existing records are in electronic format.

Are there any regulations that would prevent our information management department from scanning in research records at the end of a trial, as long as the electronic record system met all requirements of 21 CFR Part 11? My understanding of the regulations would prevent research records from being destroyed until written notice is obtained by the sponsor, and that we would need to maintain the original paper charts in addition to the scanned records. I would also think that research records being scanned into an electronic format would have all sponsor information removed and patient identifiers added back in. Most of our research records only identify a research patient by three initials and an non-identifying subject #.

In the event of an FDA audit, would printed copies of the electronic records suffice, or would original documents be requested?

Please feel free to contact me [redacted], if you need clarification on the questions addressed in this email.

Kind regards,

[redacted]