From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, June 10, 2005 8:17 AM
To: [redacted]
Subject: RE: Information required

Dear [redacted],

Please accept my apologies for the delay in replying to your inquiry about using/preserving electronic clinical trial records.

When transferring information from a paper record to an electronic record, one first needs to decide how that electronic record will be used. As explained in FDA's "Guidance for Industry Part 11 Electronic Records; Electronic Signatures-Scope and Application Guidance" (see http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf), firms need to consider their business practices when deciding what controls need to be used for electronic records. Section III.B of this guidance notes that if records required to be maintained under "predicate rules" (which, in your case, means those regulations and rules that govern the conduct of clinical trials such as 21 CFR 312, 21 CFR 812, 21 CFR 56 and 21 CFR 50) are maintained in electronic format in place of paper format, part 11 controls must be used/applied. Likewise, records that are required to be maintained that are maintained in electronic format in addition to paper format and that are relied on to perform regulated activities must meet part 11 requirements. Any records that will be submitted to FDA in electronic format too are subject to the controls required by part 11. In summary, with respect to records required to be maintained under predicate rules or submitted to FDA, when firms choose to use records in electronic format in place of paper format, part 11 would apply.

In answer to your question, if you decide to rely on the information transferred from the CRF to the database that will be used to meet regulatory requirements/obligations (e.g. those required by 21 CFR 312), the electronic records generated from this database must be complete and accurate and the computerized system/database must be part 11 compliant. All of the information originally recorded onto the CRF must appear in the database so that the electronic record can be considered accurate, adequate and complete.

However, if the database is not intended to replace the CRF, the CRF remains the "source document" (along with all of the supporting documentation upon which the CRF was generated). The CRF will need to be retained in accordance with the regulations governing record retention of clinical trial records. In such a case, the database would not have to include all of the information contained on the CRF.

As you can see, these are important policies/procedures that need to be considered when you/your firm decides to use electronic records and electronic databases. I would recommend that you describe the procedures/policies your company intends to use when selecting to use an electronic record keeping system in written SOPs and/or in the study protocol so there is no misunderstanding as to the purpose and intended used of the paper CRF and the database/electronic records.

You might want to also look at FDA's "Guidance for Industry Computerized Systems Used in Clinical Trials" (see the fourth guidance posted to the web site http://www.fda.gov/oc/gcp/guidance.html) for additional information about electronic records and the use of computerized systems in a clinical setting.

I hope this information is helpful to you.

Sincerely,

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-----Original Message-----
From: [redacted]
Sent: Tuesday, May 17, 2005 5:14 PM
To: gcpquestions@oc.fda.gov
Subject: Information required

Hello,

I need the following information:

We capture the data for the study on the CRF and enter into the database via a [redacted]

1) Do we need to enter comments on the CRF into the database. Is there a rule that all the data on the CRF have to be transferred into the database.

2) Also do we need to capture the signature on the CRF and enter into the database. The [redacted] we use converts the sign into [redacted] field. We don't think that it is useful information. So we started using initials in defined boxes. Can we keep signature / initials on CRF and not inculde in the database.

Pls help me to find instructions / requirements / guidelines in the above two matters. Thank you in advance.

Regards
[redacted]