From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, September 02, 2005 7:24 AM
To: [redacted]
Subject: RE: Certification of adherence to GCP

Dear [redacted],

Thank you for your inquiries, both this and your message dated 8/31/05. One of the best references that describes effective procedures and practices for meeting regulations the govern clinical trials is the ICH E6 Good Clinical Practice Consolidated Guidance (see http://www.fda.gov/oc/gcp/guidance.html). In general, a study conducted using the procedures and practices described in this guidance can expect to be in compliance with regulations governing good clinical practice. Since this is a guidance document and, unlike the regulations, non-binding in nature, you can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

In answer to your question about the need for certification, FDA does not certify that any facility used in the conduct of clinical studies is in compliance with GCPs, nor does FDA require that any facility be certified by any private organization.

There are certification requirements when a facility intends to use electronic signatures as the legal equivalent to handwritten signatures. The requirements for this certification are described in the FDA guidance entitled "Computerized Systems Used in Clinical Trials" (to which you make reference in your message below).

At this time, FDA has not published a specific guidance that addresses data management in any detail. General guidance on data management, again, can be found in the ICH E6 guidance referenced above. FDA is in the process of examining quality systems approaches to the oversight of clinical trials/data and there may be additional guidance from FDA at some point in the future (please visit our GCPP home page at www.fda.gov/oc/gpc for new postings).

Do you have specific questions about recommended procedures and practices recommended in FDA's guidance entitled "Computerized Systems Used in Clinical Trials" to which I can provide advice? Please let me know if there is any way I can be of future assistance.

Sincerely,

Patricia M. Beers Block
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Good Clinical Practice Program (HF-34)
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-----Original Message-----
From: [redacted]
Sent: Thursday, August 25, 2005 12:19 PM
To: gcpquestions@oc.fda.gov
Subject: Certification of adherence to GCP

With colleagues [redacted] which requires GCP
adherence. We have a computerized data management system which has been
constructed [redacted] for data entry, management and
reporting. What procedures are necessary to document that GCP is in place
(in reference to thd document entitled "Computerized Systems Used in
Clinical Trials, DRAFT GUIDANCE")? Is certification for compliance issued?

Thanks for your help.

[redacted]