From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, November 10, 2005 1:01 PM
To: [redacted]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [redacted],

Your inquiry was forwarded to our office for reply. The information you've sent looks like the certificate a firm must submit to FDA when it intends to rely on electronic signatures as the legal equivalent to handwritten signatures (see 21 CFR 11.100 at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Is your firm planning to use electronic signatures on study records? If so, this is a necessary statement your site/firm must sign if you want to rely on electronic signatures. If not, you may want to just let the CRO know that you do not plan to use electronic signatures for any of your study records (or supporting documents).

I hope this is helpful.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program
Office of the Commissioner/FDA
301-827-3340

[redacted]

-----Original Message-----
From: [redacted]
Sent: Tuesday, November 01, 2005 8:41 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [redacted]

E-Mail: [redacted]

Comments: Dear Sirs,
Our [redacted] is participating in clinical trials. Recently we have received a request from a CRO to make a statement as given below, concerning the authorisation of electronic CRF's. We are surprised by the scope of the statement ('located .... world'). Is this is indeed required by the FDA if our research physicians and principal investigators collect information in our institution, fill out the CRF's on the institutions computers and do not physically transfer the information by any means outside the institutions walls?

Thanks for your attention.

[redacted]

Date

Dear Sirs,

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that
[name of organization]
intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures.

Signature:

Printed Name:

Position: