

From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, December 22, 2005 12:27 PM
To: [redacted]
Subject: RE: [Fwd: [redacted] e-signature certification]

Dear [redacted],

I view this as more of a business issue than a regulatory issue. I have provided all of the information that explains FDA's position concerning certification. In the future, it might be best for your site/clinical investigator to get details about things like these in writing as to exactly what the CRO (working on behalf of the sponsor) expects from your organization. It sounds like this CRO/sponsor wants specific documentation from each clinical site. That's really the CRO/sponsor's call.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
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-----Original Message-----

From: [redacted]
Sent: Thursday, December 22, 2005 11:47 AM
To: GCPQuestions@OC.FDA.GOV
Subject: [Fwd: [redacted] e-signature certification]

Dear Ms Beers Block: after sharing your info with the CRO person originally requesting our office sign/send in the certification letter, I received this notice...she is basically stating that we still need to send the certification letter and that the CRO or Sponsor will now submit all letters received from investigators with the submission the Sponsor makes to FDA at end of study data collection...so my question is does the sponsor need to collect certification letters from sites for sponsor to submit w/final protocol FDA submission or is the sponsor the organization that certifies in ONE letter that all sites have met criteria? this seems to get more and more confusing!!! thanks for your help...

[redacted]

From: [redacted]
Date: Wed Dec 21 18:25:44 CST 2005
To: [redacted]
Cc: [redacted]
Subject: [redacted]e-signature certification

Hi [redacted], In the end, I believe that we both obtained the same information: once signed you may or may not elect to send the letter directly but it must be faxed to [redacted] collecting all letters that will be provided to the Sponsor and will become part of the [redacted]. Since the FDA does not provide receipt or acknowledgment of receipt, whether you do or not mail the letter cannot be verified and therefore collecting this copy is the only way that we as [redacted] can ensure compliance. Please fax to [redacted] and retain a copy for your files (this copy can be used for any and all electronic studies conducted at your site) With the best intention to fulfill our responsibilities to the Sponsor, I apologize if we caused additional work for your staff. Warm regards.

[redacted]