From: Beers Block, Patricia
Sent: Thursday, December 14, 2006 7:54 AM
To: [Redacted]
Subject: RE: Unblinded Monitors

Dear [Redacted],

FDA regulations do not explicitly address details of study monitoring, including the monitor's site visit reports. There is some coverage in FDA guidance; additional FDA guidance may be found in the International Conference on Harmonization (ICH) E6 Good Clinical Practice Consolidated Guideline accessible from FDA's GCP website (www.fda.gov/oc/gcp) through the link to "Guidances and Information Sheets" and hence to ICH E6. (See Sections 5.18.4 and 5.18.5 of the ICH E6 guideline, for example). Do note, that as guidance, these recommendations relating to monitoring reports are nonbinding, not enforceable by FDA, and alternate methods may be used.

I hope this information is helpful to you.

Sincerely,

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Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/ FDA
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Rockville, MD 20857

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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: Tuesday, November 28, 2006 6:07 PM
To: OC GCP Questions
Subject: Unblinded Monitors

Dear FDA Representative,

For blinded studies, there are sponsors who designate unblinded monitors specifically for the purposes of monitoring investigational product accountability. Blinded monitors perform all of the other routine monitoring functions, except for product accountability. Is it possible for a sponsor to utilize an unblinded monitor (e.g., contracted monitor) to perform all routine monitoring activities including such activities as source to CRF verification and product accountability or do you feel that this would be considered a problem with maintaining the blind and potential bias somehow?

Thank you,

[Redacted]