From: Toth-Allen, Jean
Sent: Thursday, April 06, 2006 8:08 AM
To: [Redacted]
Subject: RE: Query re function of monitor in clinical trial

Dear [Redacted]:

Thank you for your inquiry regarding monitoring of a clinical study.

As you are aware, both FDA regulations and guidance with regard to study monitoring are written quite broadly. If procedures involved with a study are different and/or complex enough that monitoring of them is desirable to ensure consistency across the study, there is nothing in regulations that would prevent a sponsor/monitor from observing actual procedures. However, since the rights and privacy of study subjects are a concern, the reviewing IRBs should be made aware that such observation is planned. (This can be accomplished as an amendment to the present study protocol if the study has already been reviewed and approved.) It is doubtful that an IRB would object, but they will likely insist on an additional informed consent document for those subjects that will be observed or require this information as a modification to the entire study informed consent document, listing observation by the sponsor or their representative as a possibility. If subjects were to refuse to allow such observation, it would be wise to accommodate their wishes even if they had signed a general study informed consent that listed such observation as a possibility.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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.

From: [Redacted]
Sent: Wednesday, April 05, 2006 12:07 PM
To: OC GCP Questions
Subject: Query re function of monitor in clinical trial

Dear GCPP,

[Redacted] a clinical trial, which while not intended for any FDA purpose, we intend to conduct with Good Clinical Practice. The clinical trial itself will be carried out by a clinical entity.

The trial involves the measurement of a observable parameter, blood flow, on outcomes in a dialysis population, using a new device. All patient information

related to the instrument is coded for privacy, and of course carried out under IRB supervision.

When the Director of the clinical entity and I were going over how the trial would be carried out, I mentioned that a monitor we had hired would be periodically visiting the clinical sites, both to review the data being gathered and to observe the measurement being made to ensure that our agreed-upon protocol was being followed. I took as my guide the "Guidance for Industry Guideline for the Monitoring of Clinical Investigations" on the ORA site, which includes a section on the sponsor's responsibility for the clinical investigation that states that a monitor reporting to the sponsor should visit the site of investigation to assure that:

- The facilities used by the investigator continue to be acceptable for purposes of the study.
- The study protocol or investigational plan is being followed.
- Changes to the protocol have been approved by the IRB and/or reported to the sponsor and the IRB.
- Accurate, complete, and current and current records are being maintained.
- Accurate, complete, and timely reported are being made to the sponsor and IRB.
- The investigator is carrying out the agreed-upon activities and has not delegated them to other previously unspecified staff.

To me, the second and sixth point required the monitor to observe the measurement procedure directly. The Director, however, felt that the monitor, as a Sponsor's representative, should not be present during the procedure with a patient (which only involves the arms), and suggested that a member of the clinical entity's staff observe to ensure proper protocol was being employed during the measurements, as there was no commercial interest on the part of the clinical entity.

Could you help us resolve this question as to the appropriate function of the monitor in observing the activities in this clinical trial?

Thank you.

Best regards,

[Redacted]