A question concerning a Radiologist and Form 1572From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Wednesday, March 16, 2005 4:07 PM
To: [purged]
Subject: RE: A question concerning a Radiologist and Form 1572

Dear [purged],

This is an unusual situation. It's not clear to me exactly what roles the investigator and the consulting radiologist play in this study. I have a call in to your voicemail to discuss this further. In the meantime here's my opinion. If the consulting radiologist's reports were used to determine subject's eligibility for the study and/or assess the subject's response to the test article, then the case could be made that the radiologist was assisting the clinical investigator in the conduct of the trial. If so, he could be considered a sub investigator within the meaning of 21 CFR 312.3(b) and listed on the 1572 as such.

On the other hand, based on your description of the situation below, it seems that the radiologist is not being used to qualify subjects for the study, since his assessment is well after the fact. In fact, it is not clear exactly what the purpose of the second reading of the x-rays is or what happens if there is a discrepancy between the investigator's reading and the radiologist's.It seems almost as if the radiologist is performing a quality control function for the investigator. If this is the case, one might argue the radiologist is not participating in the conduct of the study and wouldn't necessarily need to be listed as a sub investigator.

Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Unfortunately the regulations are a bit vague on who is a sub investigator. I excerpted the regulatory language below for your reference. The most important point of the 1572 in this regard is that the sponsor should be able to determine that only qualified investigators are selected to conduct the study. If a key study aspect were handled by someone other than the investigator, the sponsor should be aware of it. Identifying this individual on the 1572 or elsewhere could serve this purpose.

I'm sorry this answer isn't more definitive but this area of the regulation is

not precise and the situation you describe is unclear. Please feel free to contact me by phone to discuss this further if you would like more guidance.

Sincerely yours,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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: [purged]
Sent: Friday, March 04, 2005 10:39 AM
To: gcpquestions@oc.fda.gov
Subject: A question concerning a Radiologist and Form 1572

To an OGCP Member:
I was recently auditing a Clinical Investigator and have encountered a situation I'd like to ask about.
The trial protocol required X-ray evidence of the disease being addressed as one of the inclusion criteria. The X-ray had to pre-date randomization. The site was an established LLC whose reason for being was to perform clinical trials. The X-ray unit used was on site.
The films were read by an Investigator in a timely manner (signed dated reports found on file), and Investigator assessment was used in fulfillment of the inclusion criterion. Up to weeks later, a radiologist made a second read of the films, rendered a separate report and it was the radiologist's assessment of the disease that was entered into the source records and onto the CRFs. The radiologist was a part-time call-in who came to the research site and read the films there.
I was expecting to see the radiologist to be listed on the site's FDA Form 1572 for the trial. Would you, given these circumstances?
Your perspective will be appreciated.
[purged]

[purged]

The information transmitted in this communication is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please destroy any copies, contact the sender and delete the material from any computer.