From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, November 21, 2006 1:32 PM
To: **[Redacted]**
Subject: RE: Question Regarding the 1572 Form

Dear Ms. **[Redacted]**:

The short answers to your two questions are "yes" and "yes". Here are the details:

We are frequently asked who should be listed on the 1572, and it's a question for which there is limited guidance and not always a straightforward answer. Many people do not realize that one of the main purposes of the 1572 is to provide the sponsor with information about the clinical site and investigator qualifications which will enable the sponsor to establish and document that the investigator and site are qualified to conduct the study.

Block #6 asks for the "Names of the subinvestigators (e.g., research fellows, residents, associates) who will be assisting the investigator in the conduct of the investigation(s)." "Subinvestigator" is indirectly defined in the drug and biologics regulations (21 CFR 312.3(b):

> "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "A list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Block #6 is to capture information about individuals who, as part of an investigative team, will be assisting the investigator and who make a direct and significant contribution to the data. The decision to list an individual in Block #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant study-related duties). In general, if an individual is directly involved in the treatment or evaluation of research subjects, that person should be listed on the 1572. It would, thus, seem appropriate for the sonographer to be listed in Block #6.

Likewise, Block #4 is generally intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial (e.g., diagnostic labs performing blood work, imaging centers, cardiology labs). If the imaging center/radiology facility is performing sonograms that are required by the study protocol, then it makes sense to list it in Block #4 of the 1572.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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.

From: [Redacted]
Sent: Tuesday, November 21, 2006 6:14 AM
To: OC GCP Questions
Subject: Question Regarding the 1572 Form

Hello,

Can you tell me what the actual purpose of the FDA 1572 form is?

If a clinical trial (eg. phase 3 drug trial) required patients to, for example, have one or more echocardiograms during the study, and the echocardiograms from all patients/sites were to be sent to a central laboratory for review, would this laboratory need to be recorded in section 4 of the 1572 form and would the sonographer need to be included in section 6?

Thanks,

[Redacted]