MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, November 04, 2005 3:59 PM
To: [purged]
Cc: [purged]
Subject: RE: FDA question (re 1572)

Dear Dr. [purged]:

I apologize for the delay in responding to your e-mails. Questions about completion of the 1572 are perhaps the most common that we receive, but, unfortunately, not always the most easy to answer. The regulations do not specify how to complete the form, nor has FDA issued formal written guidance on this topic.

I can understand why the scenario you described seems so confusing. On the one hand, the community oncologists could be viewed as providing significant and direct contributions to the data being collected in the trial. On the other hand, they are simply providing routine medical care to their patients and providing copies of the medical records and progress notes to the investigator at Stanford.

I can also see a practical complication. If the 1572 is supposed to be signed before the sponsor allows the investigator to begin participation in the study, then the investigator would have to know all of the names of the community oncologists at the very beginning. However, if each oncologist has only one or two patients, there might be tens (if not hundreds) of oncologists to include on the form. And, if the condition under study were a very rare form of cancer, would the investigator really be able to identify the community oncologists who might have patients with the condition beforehand, so the names could be included on the 1572?

My best advice is a simple reminder: while many things may need to be documented in study records, not everything needs to be documented on the 1572. I thus stand by the advice I provided to [purged]: Study records should describe the types of tests/activities that may be performed by the subjects' personal physicians and note that the results will be provided to the clinical investigator. Each subject's case history should also indicate the contact information for the person who performed the test/activity and the results.

I hope this is helpful, and again, apologize for taking so long in responding to you.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24

Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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: Tuesday, October 25, 2005 11:57 AM
To: carolyn.Hommel@OC.FDA.GOV
Subject: Fwd: FDA question (re 1572)
Importance: High

Ms Hommel

Thank you for your reply. I am the chief of the [purged] and I have a few additional questions regarding this issue. Thank you in advance for providing us with guidance.

The situation you describe below is certainly common and the FDA position makes sense. However there are several other scenarios that are a bit more complex for which we are requesting an opinion.

1) An investigator at [purged] starts a study for lymphoma that involves standard chemotherapy given monthly for 6 months. The objective of the study is to measure response rates using more sensitive techniques. Many patients are referred from community oncologists and would receive their standard chemotherapy with their local physician who would see them monthly and obtain routine blood tests monitoring their progress as they would outside the context of a clinical trial. Their progress notes and labs would be sent to [purged] for entry into CRFs. The patient would be evaluated initially at [purged] for eligibility and after completing their chemotherapy would return to [purged] for response assessment including more sensitive flow cytometry. Are all of the community oncologists (and there could be a different one for each patient) considered sub-investigators? Do we have to include each of them on the 1572?

2) How about a study using a growth factor [purged] for anemia in patients with a hematologic disorder? The drug is commercially available but is supplied as part of the study and patients either self-inject or receive the injection in their local physician's office. Local laboratory data as well as any adverse reactions are reported to us by their physician. In addition, they are seen intermittently at Stanford during the course of the study. Are these physicians sub-investigators?

Thank you

[purged]

Begin forwarded message:

From: [purged]
Date: October 24, 2005 11:20:14 AM PDT
To: [purged]
Subject: Fwd: RE: FDA question (re 1572)

Dear All,

[purged] obtained an answer from the FDA regarding the inclusion of local physicians in the FDA1572. Please see the below attached email.

Kind Regards,
[purged]

X-Sieve: CMU Sieve 2.2
From: OC GCP Questions <GCPQuestions@OC.FDA.GOV>
Sender: "Hommel, Carolyn - OC" <Carolyn.Hommel@OC.FDA.GOV>
To: [purged]
Cc: [purged]
Subject: RE: FDA question (re 1572)
Date: Mon, 24 Oct 2005 13:56:58 -0400
X-Mailer: [purged]
Hi, [purged]:

We have received this question more than once, and you are correct--there isn't a clear answer in FDA's regulations or guidance at this time. This is the advice my office has provided in the past:

When a subject lives a long distance from the clinical trial site, it may not be convenient or practical for the subject to return to the site to perform routine follow-up procedures (e.g., blood or other lab test, routine eye exam). To reduce the inconvenience for study subjects, the study protocol may allow a subject's personal physician to perform a specific test or activity. In such cases, FDA does not view the personal physician as a sub-investigator, and does not expect him/her to be listed

on a 1572. Instead, study records should describe the types of tests/activities that may be performed by the subjects' personal physicians and note that the results will be provided to the clinical investigator. Each subject's case history should also indicate the contact information for the person who performed the test/activity and the results.

I hope this is helpful.

Carolyn

Carolyn Hommel
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-----Original Message-----

From: [purged]

Sent: Thursday, October 20, 2005 11:34 AM

To: Hommel, Carolyn - OC

Cc: [purged]

Subject: RE: FDA question (re 1572)

Importance: High

Hi Carolyn,

As always, thanks for your prompt response. The following is the questions/situation that I need some guidance on:

We at [purged] (more specifically the [purged]) are a major referral center. As such, our clinical trial population visits our medical center f/ locations both near and far. Our clinical trial patients are seen @ [purged] during their monthly scheduled visits according to protocol guidelines. There are times though when the protocol indicates that for example a blood test needs to be performed every week. It is not always convenient or practical for our patients to come to [[purged] (especially if they live out of state or far from our Center) for a simple CBC or chemistry test. In this scenario, will their local Drs. be considered sub-PI's in the eyes of the FDA? If so, do they need to be listed on the FDA form 1572? It seems like there is no clear cut answer but if you could refer me to the appropriate information sheets that would be most helpful.

Kind Regards,

[purged]

At 06:09 AM 10/20/2005, you wrote:

Hi, [purged],

Although you can call us at the number shown below, our office generally prefers having all questions come through our GCP Questions e-mail account. (gcpquestions@oc.fda.gov ). That way, if a staff member is out of the office, the question will get into the queue and can be assigned to the next available person.

Carolyn

Carolyn Hommel

Consumer Safety Officer

Good Clinical Practice Program

Office of Science and Health Coordination

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-----Original Message-----
From: [purged]
Sent: Wednesday, October 19, 2005 6:51 PM
To: Hommel, Carolyn - OC
Cc: [purged]
Subject: RE: FDA question (re 1572)
Importance: High

Hi Carolyn,

I hope you are well. I have a question regarding the FDA form 1572 and who should be or should not be listed on the 1572 under the sub-investigator section. Is there a phone number that I can reach you at to relay my question?

Thanks,

[purged]

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[purged]
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