From: OC GCP Questions
To: [redacted]
Subject: RE: Form 1572 Question
Date: Friday, July 10, 2015 10:02:00 AM

Dear [redacted]

Thank you for your responses to my questions. Your emails provide very minimal information about this study, so this response is based on the following assumptions:

- The subject is in long-term follow-up for a study and no longer receiving treatment, but is seeing his/her physician for clinical purposes at a site that is not listed on the 1572, although the physician is listed on the 1572 as a sub-investigator.
- The principal investigator (PI) has delegated authority to the sub-investigator to discuss the consent revision with this subject and the study sponsor concurs with this decision.
- The sub-investigator is familiar with the amendment and is qualified to discuss the amendment and address any questions the subject may have.
- None of the contact information in the consent form has changed.
- The IRB has been or will be notified.

You asked if the patient can be "re-consented" for an amendment to the study at this alternate site. Since the physician is already a sub-investigator, the subject may be "re-consented" at this alternate location and documentation provided in the study record, if, as noted above, the study sponsor agrees, the PI has delegated authority to the sub-investigator, and the sub-investigator is qualified to do so.

It is not clear from your emails whether only the consent process will occur at this alternate site, or whether additional follow-up visits will also occur here. Although you indicate no treatments will be provided at this site, the principal investigator, study sponsor and IRB should be notified if any interventions that are considered part of the study for the subject's long-term follow-up will be conducted at this location (e.g., obtaining vital signs, lab work, ECGs, etc.).

The PI is responsible for ensuring that patients are followed in accordance with the protocol and supervising study staff. You may also find the *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* helpful. They can be found on FDA's website at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf and *Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects* http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS

Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, July 08, 2015 2:36 PM
To: OC GCP Questions
Subject: RE: Form 1572 Question

Please see my answers to your questions in red below:

1. Can you explain what you mean by "open clinical trial", please? The study has IRB approval and we have patients either on treatment or in follow-up.
2. Is the patient's physician listed on the 1572 (e.g., sub-investigator), even if this specific office is not? Yes, the physician is listed on the 1572.

Thanks,

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Wednesday, July 08, 2015 2:33 PM
To: [redacted]
Subject: RE: Form 1572 Question

Dear [redacted],
I need a bit more information before I can help you.

1. Can you explain what you mean by "open clinical trial", please?
2. Is the patient's physician listed on the 1572 (e.g., sub-investigator), even if this specific office is not?

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Wednesday, July 08, 2015 12:26 PM
To: OC GCP Questions
Subject: Form 1572 Question

Hello,

We have an open clinical trial here in ώǋŜŘǀ·ŎǘŜŘ6. We have a subject who is in long-term follow up and is visiting his doctor for clinical purposes (at a site not listed on the 1572). The sponsor recently submitted an amendment which requires reconsenting this subject. This subject lives 1.5 hours away from where he visits his physician.

Can the physician consent this subject even though this particular office is not listed on the 1572? No research treatment procedures will take place. The only procedure related to his involvement on the research trial is signing the updated informed consent.

Thank you,

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