From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, April 17, 2006 5:12 PM
To: '**[Redacted]**
Subject: RE: Form FDA 1572

Dear Ms. **[Redacted]**:

Your question about listing ethics committees (ECs) on the 1572 was forwarded to me for a response. I apologize for the delay in answering your e-mail.

If I understand your question correctly, the EC of the country coordinator for the study will review/approve the study, and a local EC for a particular investigator may also review/approve each study. Since the decision of both ECs would be required for the study to proceed, I would recommend that you list both ECs on the 1572.

At this time, there is no other guidance on how to complete the 1572. However, it is something we are looking into.

I hope this is helpful.

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)
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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: Monday, April 03, 2006 10:09 AM
To: OC GCP Questions
Subject: Form FDA 1572

<< Message: Untitled Attachment >> **[Redacted]**

Please advise, which EC should be listed on the FDA1572 form?

According to local law - if a study is conducted in multi centres by different Investigators with the same protocol the sponsor appoints a country coordinator. An opinion of the Ethics Committee

appropriate for a country coordinator is applicable for all sites.

However, the EC of country coordinator, that gives opinion of the study informs other ECs appropriate for other Investigators/sites, where the study will be conducted. Those ECs might put up restriction regarding participation of the Investigator or the site. If no restriction is sent to the EC appropriate for country coordinator within 14 days it means that the participation of the Investigator/site is accepted.

Should be EC that gives opinion of the Investigator/site be also listed or only the EC of country coordinator that approves and reviews the study?

Is any guideline for completing Form FDA 1572 available?

Thank you for reply.

With regards,

[Redacted]