From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, November 03, 2005 3:47 PM
To: [purged]
Subject: RE: 1572 section5

Dear Ms. [purged]:

This is in response to your question on the DRUGINFO Comment Form about listing ethics committees on the Form FDA 1572. I apologize for the delay in responding to you.

There is not any specific written guidance about completing the 1572.

In the first scenario that you provided, the "Central" ethics committee should definitely be listed on the 1572 because it is providing approval for the study. Whether the "local" ethics committee should also be listed is not as clear. It certainly doesn't do any harm to list both on the form, and provide an explanation about the respective roles that each has assumed for the study.

In the second scenario that you provided, because both ethics committees are issuing an approval for the study, both should be listed in item 5 of the 1572.

I hope this is helpful, and again, apologize for taking so long to answer your e-mail.

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

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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.

-----Original Message-----
From: [purged]
Sent: Monday, October 10, 2005 5:43 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Dear Madam,
dear Sir,

I am contacting you with a question regarding form 1572 "Statement of Investigator", section 5 (IRB responsible for review and approval).

With EU-Directive 2001/20/EC having taken on effect, there are now basically two different procedures in European countries, depending on the country where a clinical trial is conducted/ submitted to ethics committees (IEC):

1) the study is submitted to a Central Ethics Committee, with information on the local IECs + sites planned to participate in the study, and the local IECs are then contacted by the central IEC and asked to comment on the ability to conduct the study in question at "their" site. Only the Central IEC may eventually issue an approval; however, the local IECs comment on "their" site and might comment on study documentation such as the protocol. These comments are not binding for the Central IEC, but will in most cases be taken into account in its final assessment.

2) the study is submitted to both a Central IEC and - subsequently - to a local IEC. Both committees may issue an approval of the study.

My questions to form 1572 are:
a)Do both Central and local IEC have to be recorded in section 5 for the above-described procedure 1)? If not, which IEC (central or local) has to be recorded? b)Do both Central and local IEC have to be recorded in section 5 for the above-described procedure 2)?

Thank you in advance for your advise.

Sincerely,
[purged]