From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, May 02, 2005 12:23 PM
To: [pasqed]
Cc: Lee, Bonnie (CBER/GCINFO)
Subject: RE: Drugfinfo Comment Form FDA/CDER Site

Dear [pasqed],

We do understand that outside the United States, Institutional Review Boards (IRB) are frequently called Institutional Ethics Committees and serve the same function as an IRB here. If a non-US study is conducted under an IND, then all FDA IND regulations, including the requirement to obtain a signed 1572, must be met. If a study is conducted outside of the U.S. and it is not conducted under an IND, the investigator would not be required by FDA to sign a 1572. For non-US studies conducted under an IND, the 1572 is required. But the form itself requires the investigator to commit to (among other things) ensuring that the IRB that reviews and approves the research will comply with 21 CFR 56. International ethics committees (ECs) that review research may not meet all the requirements for IRBs in FDA's regulations (for example, IRB membership (21 CFR 56.107)). An investigator can sign the 1572, and request a waiver of applicable IND requirements so that the EC conforms to US requirements.

Under 21 CFR 312.10, sponsors may request waiver of applicable IND requirements. In other words, the sponsor of an IND study being conducted at a non-US location can request a waiver of the requirement that the ethics committee that reviews the study comply with FDA's requirements for IRBs. By describing and providing information about the EC that will review the study, the sponsor can show that although the EC may not meet a particular requirement in 21 CFR 56, nevertheless, in all other ways the EC complies with existing requirements for ethical review of the study and assurances the protection of the rights and welfare of the human subjects. FDA can then determine if the information provided by the sponsor is sufficient to grant the waiver. The waiver may be submitted wither in an IND or in an information amendment to an IND.

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: [pasqed]
Sent: Thursday, April 07, 2005 12:31 AM
To: druginfo@cder.fda.gov
Subject: Drugfinfo Comment Form FDA/CDER Site

Name: [pasqed]

E-Mail: [pasqed]
Comments: Dear Sir,
I have a query pertaining to FDA 1572 Form.
I was going through the FDA 1572 form.
There in the Section 5 of this form it has been mentioned as." Name and Address of the Institutional Review Board (IRB) that is responsible for Review and Approval of the Study(ies)".

Sir, in some places, Institutional Ethics Committee (IEC) dealt with the ethical aspects related to a Clinical Trial/Bioequivalence Study in place of Institutional Review Board (IRB).

Sir, it is my suggestion that can the "IRB" in the Section 5 of FDA 1572 be changed to "IRB/IEC" or the "any ethical committee" or any other "suitable words" which will cover the broader range of Ethical review committees?

with kind regards,
[pasqed]