MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, October 04, 2005 10:33 AM
To: [purged]
Subject: RE: Form 1572 in foreign studies

Dear Dr. [purged]:

This is in response to your e-mail to Dr. Lepay, in which you asked when a Form FDA 1572 would be required for studies conducted outside of the United States.

If a non-US study is conducted under an Investigational New Drug Application (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, then the investigator would not be required by FDA to sign a 1572.

We are aware that a non-US investigator may be reluctant to sign a 1572, because the investigator cannot commit to all of the requirements on the form (e.g., institutional review board (IRB) membership per 21 CFR 56.107)). If this is a situation that you encounter, then the following information may be helpful to you.

IRB review and approval is required before a study can be initiated under an IND [21 CFR 56.103(a)]. FDA may waive any of the IRB requirements for specific research activities or for classes of research activities otherwise covered by the IRB regulations [21 CFR 56.105], but FDA uses the waiver provision only when alternative mechanisms for ensuring protection of the rights and welfare of human subjects are acceptable. The most common circumstance for which FDA receives a waiver request is when a sponsor wishes to conduct a foreign clinical study under an IND. In this case, typically an Independent Ethics Committee (IEC) that operates in accordance with Good Clinical Practice (GCP) is utilized instead of a US IRB. Although its membership and functions for assuring human subject protection are comparable to an IRB, an IEC may not meet all of the IRB requirements contained in 21 CFR part 56.

For foreign studies, an IRB waiver request should contain a description of alternative mechanisms for assuring human subject protection to be used by the sponsor. As noted above, it would generally be acceptable for a waiver request to state that the sponsor intends to use an IEC that complies with GCP instead of an IRB that complies with all of the requirements contained in 21 CFR part 56.

The sponsor should submit the waiver request to the IND under which the study will be conducted in the appropriate review division in the Center for Drug Evaluation and Research (CDER) or in the Center for Biologics Evaluation and Research (CBER).

The sponsor will be informed by the agency in writing whether the waiver request is denied or granted. If a waiver is granted, the sponsor should have investigators attach a copy of the letter granting the waiver to the signed 1572 in the investigator's record.

I hope this information is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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, September 26, 2005 10:37 AM
To: david.lepay@fda.hhs.gov
Subject: Form 1572 in foreign studies
Importance: High

Dear Dr Lepay

You may recall us meeting at the ACRP Annual Conference [purged]. I enjoyed your concluding lecture enormously. During that talk you referred to the use of the Form 1572 (Investigator Statement) in US and foreign studies and, I believe, confirmed that it was not necessary to file the 1572 for studies conducted outside the

USA (unless they were part of an IND).

Of course, it is expected that studies be performed in accordance with GCP (notably ICH GCP) and that if followed this, together with an investigator agreement between sponsor and investigator confirming that GCP will be followed, would be adequate.

Please can you advise me if this is still the current thinking within the FDA. Please can you advise me when a 1572 should be used for studies conducted outside the USA, if at all.

Your help would be really appreciated.
With best wishes
[purged]