FDA Form 1572 and Foreign Clinical Trial SitesFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 15, 2005 3:13 PM
To: [purged]
Subject: RE: FDA Form 1572 and Foreign Clinical Trial Sites

Dear [purged], I suspect that the answer depends not only on the sponsor and the nature of the studies, but also on the review division at FDA responsible for the IND. It would seem to me that it the waiver requested were for studies conducted under a single IND and the same conditions existed for each study, it might make sense to have a single request. But, that is up to the IND division. Because the requirement for IRB review and approval is one that needs to occur prior to the conduct of the study, any waiver of all or part of the IRB regulatory requirements should also be prior to study initiation and enrollment. I hope this is helpful to you.

Have a great weekend.

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: [purged]
Sent: Tuesday, April 12, 2005 3:44 PM
To: GCPQuestions@OC.FDA.GOV
Subject: RE: FDA Form 1572 and Foreign Clinical Trial Sites

Dear Bonnie,

Thank you for your response to my initial question. In regards to requesting an IRB waiver from the FDA, would it be acceptable to request a waiver at the IND level (waiver for all studies with non-U.S. sites under the IND), or does the waiver need to be per protocol, or per IRB? Also, does this waiver need

to be granted by the FDA prior to study initiation and enrollment?

Any additional guidance would be appreciated.

Thank you,

[purged]
-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Tuesday, March 29, 2005 8:20 AM
To: [purged]
Subject: RE: FDA Form 1572 and Foreign Clinical Trial Sites

Dear [purged],

If a non-U.S. stud is conducted under an IND, then all FDA IND regulations, including the requirement to obtain a signed SF-1572, must be met. If a non-U.S. study is not conducted under an IND, then submission of a 1572 is not required. However, 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-U.S. location can request a waiver of the requirement that the ethics committee that reviews the study comply with FDA's requirements for IRBs (the main difficulty with the 1572). By describing and providing information about the IEC that will review the study, the sponsor can show that although the IEC may not meet a particular requirement in 21 CFR 56, nevertheless, in all other ways the IEC complies with existing requirements for ethical review of the study and assures 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 either in an IND or in an information amendment to an IND. See 21 CFR 312.10.

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: [purged]
Sent: Monday, March 28, 2005 2:51 PM
To: gcpquestions@oc.fda.gov
Subject: FDA Form 1572 and Foreign Clinical Trial Sites

Good Afternoon,
My name is [purged] and I work in Regulatory Affairs at [purged]. Currently we are developing one clinical trial protocol that will be submitted to the IND that will include trial sites both inside and outside the U.S. We would like to receive feedback from the Agency on the requirement to collect the FDA form 1572 from clinical trial sites outside the United States. Does the Agency expect to have 1572's from the investigators in foreign sites? If not, what documentation would be required by the Agency for those sites outside of the U.S.?
The ICH E6 guideline defines "applicable regulatory requirements" as "any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products of the jurisdiction where the trial is conducted." The CFR requires a 1572 for each investigator prior to starting the clinical investigation, whereas the ICH E6 guidance states that the investigator ..."should meet all the qualifications specified by the applicable regulatory requirements.....". Since the FDA accepted this document as current GCP thinking, does this mean that the FDA Form 1572 would not be required from investigators in sites outside the U.S.?
We wanted to obtain the FDAs perspective on this issue so that we can develop a policy for our company with regards to this issue. Any feedback would be greatly appreciated.
Thank you,
[purged]