MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, March 18, 2005 10:57 AM
To: [purged]
Subject: RE: Form 1572

Dear [purged],
Your question was referred to me for a direct reply. You are correct that FDA 1572s are required for studies that are conducted under an IND. However, foreign studies can be conducted that are not conducted under an IND. Perhaps this is where the confusion lies in whether a 1572 is required of all clinical investigators conducting studies at your study sites.
Under 312.120, this regulation acknowledges the fact that foreign clinical studies might not be conducted under an IND and describes the criteria under which FDA will accept foreign clinical studies not conducted under an IND. The regulation states, in part (I've truncated it; you may want to look at the complete cite at):
"Sec. 312.120 Foreign clinical studies not conducted under an IND.
(a) Introduction. This section describes the criteria for acceptance by FDA of foreign clinical studies not conducted under an IND. In general, FDA accepts such studies provided they are well designed, well conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community. Studies meeting these criteria may be utilized to support clinical investigations in the United States and/or marketing approval. Marketing approval of a new drug based solely on foreign clinical data is governed by § 314.106.
(b) Data submissions. A sponsor who wishes to rely on a foreign clinical study to support an IND or to support an application for marketing approval shall submit to FDA the following information:
(1) A description of the investigator`s qualifications;
(2) A description of the research facilities;
(3) A detailed summary of the protocol and results of the study, and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records;
(4) A description of the drug substance and drug product used in the study, including a description of components, formulation, specifications, and bioavailability of the specific drug product used in the clinical study, if available; and
(5) If the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126.
(c) Conformance with ethical principles. (1) Foreign clinical research is required to have been conducted in accordance with the ethical principles stated

in the "Declaration of Helsinki" (see paragraph (c)(4) of this section) or the laws and regulations of the country in which the research was conducted, whichever represents the greater protection of the individual.
(2) For each foreign clinical study submitted under this section, the sponsor shall explain how the research conformed to the ethical principles contained in the "Declaration of Helsinki" or the foreign country`s standards, whichever were used. If the foreign country`s standards were used, the sponsor shall explain in detail how those standards differ from the "Declaration of Helsinki" and how they offer greater protection.
(3) When the research has been approved by an independent review committee, the sponsor shall submit to FDA documentation of such review and approval, including the names and qualifications of the members of the committee. In this regard, a "review committee" means a committee composed of scientists and, where practicable, individuals who are otherwise qualified (e.g., other health professionals or laymen). The investigator may not vote on any aspect of the review of his or her protocol by a review committee.
(4) The "Declaration of Helsinki" states as follows: ..."
So the short answer to your question is "it depends" on whether the clinical studies conducted in a foreign country are conducted under an IND (e.g., an 1571 has been submitted by the sponsor that makes reference to the foreign study sites). If the studies are covered by an IND, a 1572 needs to be entirely completed. If, on the other hand, the study is not conducted under an IND, a 1572 does not have to be completed but the criteria for FDA's acceptance of the study must be met.
I hope this information is helpful to you. Please let me know if I can be of any further assistance.
Sincerely,
Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340
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: Friday, March 18, 2005 5:54 AM
To: Lepay, David
Subject: RE: Form 1572

Der Dr. Lepay,

Thanks for your response some time ago!
I would like to extend the question and ask if it would be possible to alter the form to suit European investigators? Can something be crossed out on the form, for instance?
I have now had experiences from investigators refusing to sign the form 1572, because they do not
believe they can/should work according to US laws.
This have had the effect that those particular investigators have not been included in our study,
which is a great pity.
The other way - having Wyeth to perform non-IND studies seems not even worth a try, I'm afraid.

With wishes for a nice Easter break!
Kind regards,

[purged]

>>> "Lepay, David" <DLepay@OC.FDA.GOV> 2004-10-08 15:26:50 >>>

Dear Mr. [purged]:
There is no FDA requirement for a study site outside of the United States to operate under a U.S. IND. FDA has regulations/requirements for the acceptance of non-U.S., non-IND studies (see FDA's GCP website www.fda.gov/oc/gcp; link to "Good Clinical Practice/Clinical Trial Regulations" for current 21 CFR 312.120 and 21 CFR 314.106; link to "Guidances and Information Sheets" for an April 2001 guidance on the Acceptance of Foreign Clinical Studies; and link to "Proposed Regulations and Draft Guidances" for a proposed revision to 21 CFR 312.120 that is just completing its comment period (i.e., not yet finalized)).
There is no requirement for a Form 1572 in non-U.S., non-IND studies, although FDA's proposed revision to 312.120 (cited above) recommends as (non-binding, non-enforceable) guidance that sponsors obtain attestations (similar to the "Commitment" section of the 1572) from investigators in non-U.S., non-IND studies/sites.

If, however, a sponsor voluntarily commits to conduct a non-U.S. study (or the operation of non-U.S. sites in a multi-national study) under a U.S. IND and its provisions, then the 1572 must be collected from all investigators under

the IND (including non-U.S. investigators), and the commitments on the 1572 are expected by FDA to be followed by all clinical investigators so covered.

I hope this answers your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

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-----Original Message-----
From: [purged]
Sent: Friday, October 08, 2004 9:10 AM
To: gcpquestions@oc.fda.gov
Subject: Form 1572

Dear Sirs,

I wonder if form 1572 should be used for IND studies performed in Europe?

Kind regards,
[purged]