From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, March 11, 2005 10:00 AM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Marlene,

Your question was referred to our office (Good Clinical Practice Program) 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 Canadian 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 Canada are conducted under an IND (e.g., an 1571 has been submitted by the sponsor that makes reference to the Canadian study sites). If the studies are covered by an IND, a 1572 needs to be 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: CDER DRUGINFO
Sent: Thursday, March 03, 2005 1:28 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Monday, February 28, 2005 1:03 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: I was requesting canadian clinical sites to complete FDA 1572s before they can participate in our US clinical studies. A new Clinical Research Associate came on board and said that Canadian investigators do not have to complete FDA 1572s, as they do not fall under FDA regulations. I know that she is wrong. According to CRF 21, all investigators participating in a particular study, must complete the FDA 1572 and submit required documents to the Sponsor. She still disagrees and she has told me to stop collecting FDA 1572s from the canadian clinical sites, unless I can show her proof that they are obligated to complete FDA 1572s when they participate in US IND initiated clinical studies.

So, my question is "Are International clinical investigators obligated to complete the FDA 1572 when they participate in US IND initiated clinical studies? If so, where can I find that written in the regulations?"

Thank you very much for your time and assistance in this matter.

Sincerely,
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