From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, July 14, 2006 2:25 PM
To: [purged]
Subject: RE: Publications

Dear [purged]:

Your question, as to whether there are requirements to publish the results of clinical trials, was forwarded to me for a response.

There is only one instance, that is, emergency research studies involving an exception from informed consent under 21 CFR 50.24, in which the Food and Drug Administration (FDA) requires "[p]ublic disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population and its results..." (See 21 CFR 50.24(a)(7)(iii)).

In the preamble to these regulations, the agency expressed its opinion, as follows:

"...it is necessary to provide comprehensive summary data from the completed trial to the research community in order to permit other researchers to assess the results of the clinical investigation. The agency thinks that there must be a scientific need to conduct clinical investigations involving subjects who are unable to consent; if previous investigations have already provided the scientific answer, this should be shared broadly with the research community. Sufficient information may be contained in a scientific publication of the results of the completed investigation; in other instances, it may need to be supplemented by additional information. The agency has modified §50.24(a)(7)(iii) to clarify that the information to be disclosed is to include the demographic characteristics (age, gender, and race) of the research population." [See 61 Federal Register 51498, October 2, 1996, comment #75 at 51516]

Such public disclosure could, of course, be accomplished through publication in a medical journal, but the regulations do not specifically require that it be done in that manner.

With respect to publication of the results of other studies conducted under an Investigational New Drug Application (IND), FDA's regulations do not require sponsors to publish their data. Data submitted to an IND is proprietary, and remains confidential commercial information unless it is released by the sponsor

or included within an approved New Drug Application (NDA). Results of these studies do, however, have to be reported to FDA in annual reports or sooner, if important. And, FDA reviews all data, not just published data, submitted to the NDA when making determinations of safety and effectiveness. FDA may also refer to data reported to the underlying IND, in addition to the information submitted to the NDA. FDA can require companies to modify product labeling based on such data, but that, of course, is not the same as a publication.

I hope this is helpful to you.

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.

From: [purged]
Sent: Sunday, July 02, 2006 3:09 AM
To: OC GCP Questions
Subject: Publications

TO WHOM IT MAY CONCERN,
I would like to know if one is obliged to publish the results of his clinical trial?
As per Helsinli declaration I understand that one must publish accurate

results but, it is not mentioned whether results must be published.
Thank you in advance,
[purged]