From: Toth-Allen, Jean
Sent: Tuesday, April 04, 2006 1:35 PM
To: [purged]
Subject: RE: Good Clinical Practice

Dear [purged] :

Thank you for your inquiry regarding publication of study data.

As you probably have noted, FDA regulations governing the conduct of investigational studies (21 CFR part 312 for pharmaceuticals and part 812 for devices) do not address the publication of study results. The ICH GCP document, which is available at http://www.fda.gov/cder/guidance/959fnl.pdf and which FDA has adopted as official guidance, only states that the publication policy can be included in the study protocol (6.1G) if not addressed in a separate agreement. The implication here is that publication policy is something agreed upon between the study sponsor and the participating investigators before initiation of the study. Such a legal agreement would not be under FDA's purview. As you note, many peer-review publications also have specific rules with regard to publishing study data, which would also be outside of FDA's purview. FDA regulations do, however, require that an investigational site maintain copies of all study documents for the prescribed retention period (312.62 and 812.140(a) and (d)).

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OMC, Office of the Commissioner, US 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(d)(6) 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, April 03, 2006 1:58 PM
To: OC GCP Questions
Subject: Good Clinical Practice

I am in negotiations with a company about conducting a study and there is some discussion about who owes the data, publication, etc. I have read the GCP guidelines and can't find anywhere where it states clearly that it is an ethical requirement that the data should be published and/or that the investigator has freedom from the sponsor to publish it. I have read AMA's guidelines which seem even more strict than the GCP and I have read other material consistent with GCP that the investigator have freedom to publish all findings. Any guidance about this would be greatly appreciated. Dan
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[purged]