From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, June 26, 2006 2:18 PM
To: [purged]
Subject: RE: Investigator own IND study

Dear [purged]:

FDA regulations do not define "Trial Master File," although, as you know, our regulations do require certain documents to be maintained in a clinical trial. The only place in the ICH E6 guidance where "Trial Master File" is mentioned is in the "Introduction" to Section 8, Essential Documents for the Conduct of a Clinical Trial, which states, "Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office." The term "trial master file" is used in the EU directives, so it may be helpful for you to check for the term in the various EU directives pertaining to clinical trials.

By "investigator-own" IND trial, I'm assuming that you are referring to an investigator who is serving as a "sponsor-investigator," (i.e., "an individual who both initiates and conducts an investigation and under whose immediate direction the investigational drug is administered or dispensed"). Under our regulations, if an investigator is serving as a sponsor-investigator, then he is required to maintain records as both a sponsor AND as an investigator. See the definition for "sponsor-investigator" in 21 CFR 312.3, and the regulations pertaining to record keeping requirements: 21 CFR 312.57 and 312.68.

Having said that, your initial question is not completely clear to me. Does "sponsor" refer to an entity whose sole involvement is supplying an investigational product to the investigator? In that case, it wouldn't make much sense for the entity that supplies the investigational product to a sponsor-investigator to also have to maintain the records that you describe--as that would be the responsibility of the sponsor-investigator.

Carolyn
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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: Tuesday, June 13, 2006 11:15 AM
To: OC GCP Questions
Subject: Investigator own IND study

Dear Carolyn and colleagues,

I recently received this GCP question from a colleague. It concerns Investigator's own IND studies. I would appreciate your opinion on this matter.

"I have a client who is creating complete Trial Master Files (TMF) for Investigator own IND studies. While critical documentation is certainly expected, I personally see no reason to have a complete TMF at the sponsor's site for every Investigator own IND trial. However, I find no reference in E6 on this issue."

You help and thoughts are very much appreciated.

Thanks and regards,
[purged]