

From: OC GCP Questions
Sent: Thursday, November 19, 2015 4:52 PM
To: [REDACTED]
Subject: RE: Financial Disclosure

Dear [REDACTED]:

FDA's Guidance on Financial Disclosure by Clinical Investigators (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>) has the following Q&A's that are relevant to your question:

D6 Q: What obligations does the clinical investigator have under the financial disclosure regulations?

A: Clinical investigators are to provide sponsors sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements (see 21 CFR §§ 54.4, 312.53(c)(4), 312.64(d), 812.43(c)(5) and 812.110(d)). Clinical investigators must provide this information to sponsors and also promptly update the information if any relevant changes occur during the course of the investigation and for one year following the completion of the study (see 21 CFR §§ 54.4(b), 312.53(c)(4), 312.64(d), 812.43(c)(5) and 812.110(d)).

C8 Q: The regulation requires that investigators provide information on financial interests and arrangements during the course of the study and for one year after completion of the study (see 21 CFR § 54.4(b)). What does "during the course of the study" mean? What does "completion of the study" mean?

A: "During the course of the study" refers to the time from the date the clinical investigator entered into an agreement with the sponsor to conduct the study until the completion of the study. For the purposes of financial disclosure under part 54, completion of the study means that all study subjects have been enrolled and follow-up of primary endpoint data on all subjects has been completed in accordance with the clinical protocol. Many studies have more than one phase (e.g., a study could have a short-term endpoint and a longer term follow-up phase). "Completion of the study" here refers to the part of the study that is being submitted in the application. If there were a subsequent application based on longer term data, completion of the study would be defined using completion of follow-up for the longer term data. An applicant is not required to submit updated financial information to FDA after submission of the application, but applicants must retain complete records (21 CFR § 54.6). Where there is more than one study site, the sponsor may consider completion of the study to occur when the last study site is complete, or may consider each study site individually as it is completed.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGo odClinicalPractice/default.htm> .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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: [REDACTED]
Sent: Tuesday, November 17, 2015 2:47 PM
To: OC GCP Questions
Subject: Financial Disclosure

To Whom It May Concern:

Can you please reiterate the requirements of 21 CFR Part 54 in regard to the number of financial disclosures that an investigator must complete during the course of a study? My understanding was that a financial disclosure form is to be completed at the beginning of the study and, if nothing changes in regard to financial issues through to 1 year after the study is closed, no additional disclosure forms need to be completed. Pls advise if requirements have changed.

Thanks.

[REDACTED]