

From: OC GCP Questions
Sent: Friday, April 17, 2015 4:24 PM
To: [REDACTED]
Subject: RE: Timing question

Dear [REDACTED],

My sincere apologies for the delay in our response. You are correct in that the IND/IDE Sponsor (in this case the Sponsor-Investigator) should collect the financial disclosure information prior to the start of the study. The information should be collected prior to the start of a study and be promptly updated throughout the course of the study and for one year following the completion of the study (21 CFR 312.52 and 812.43). FDA does not specify how the financial disclosure information should be collected from the investigators. The forms (Form FDA 3455 Disclosure or Form FDA 3454 Certification) are required to be submitted with the marketing application that is submitted to FDA.

You may find the following guidance document to be useful on Financial Disclosure by Clinical Investigators:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

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, March 31, 2015 4:08 PM
To: FDA GCP Email (gcp.questions@fda.hhs.gov)
Subject: Timing question

Dear FDA,

I have a question about the timing of collection of form 3454, FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS.

Should the sponsor-investigator collect this form in an ongoing fashion and then submit, at the time of marketing application, the forms to the FDA or is it acceptable for the sponsor-investigator to collect financial interest and other conflict of interest information in a meaningful way, and then at the time of

submission of the marketing application, include the form 3454?

Sincerely,

[REDACTED]