From: OC GCP Questions
To: [redacted]
Subject: Financial Disclosure Follow Up
Date: Tuesday, April 22, 2014 5:38:29 PM

Good afternoon --

Below is what we have advised writers in the past regarding financial disclosure follow-up.

The recently revised FDA guidance "Financial Disclosure by Clinical Investigators" (available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf) includes information to address your question section IV.E.4:

Q: Is the IND/IDE sponsor responsible for obtaining 1-year follow-up financial information from clinical investigators?

A: As noted in response to Question E.2 above, the IND/IDE sponsor is required to obtain financial information from clinical investigators before permitting the investigators to begin participation in an investigation and to obtain the investigator's commitment to promptly update this information if any relevant changes occur during the course of the study and for one year following the completion of the study (21 CFR §§ 312.53 and 812.43). The regulations do not specifically require the IND/IDE sponsor to obtain information from clinical investigators one year following completion of the study. The regulations, however, do require IND/IDE sponsors to maintain complete and accurate records concerning all financial interests and arrangements of clinical investigators subject to part 54 (see 21 CFR §§ 312.57(b) and 812.140(b)(3)) and to secure investigator compliance with the regulations (see 21 CFR §§ 312.56(b) and 812.46(a)). Therefore, an IND/IDE sponsor should take steps to ensure clinical investigator compliance, such as reminding the clinical investigators of the requirement to promptly update their financial information when any relevant changes occur during the study and for one year following completion.
The regulations do not specifically require sponsors to contact clinical investigators one year following study completion. The regulations require sponsors to obtain financial disclosure information from clinical investigators prior to the investigator initiating participation in the study (21 CFR 312.53 and 812.43). The information obtained at this point is likely to be very limited because the financial information required to be obtained is from the period of time during the conduct of the investigation and for one year following study completion. So, this initial collection of financial disclosure information would likely be incomplete.

During the course of the study and for one year following study completion, the initially reported financial interests and arrangements may change and the clinical investigators may receive significant payments of other sorts or compensation that could be affected by study outcome that would need to be reported. The regulations require the clinical investigators to promptly provide updates to the sponsor if any relevant changes occur in their financial disclosure information during the course of the investigation and for one year following study completion (21 CFR 54.4(b)).

Sponsors are also required to secure investigator compliance with the regulations (21 CFR 312.56(b) and 812.46(a)). A sponsor could decide that reminding clinical investigators about their obligations related to updating their financial disclosure information one year following study completion is an appropriate step to take to secure compliance but the regulations do not specifically require this.

The regulations also require that the certification and/or disclosure information provided to FDA is complete and accurate (21 CFR 54.4). There may be situations where a sponsor is uncertain whether the financial disclosure information for a clinical investigator is complete and accurate. If so, the sponsor should act with due diligence to ensure the information is complete and accurate (21 CFR 54.4). The guidance includes a discussion of due diligence in section IV.B.7, which provides examples of methods a sponsor may want to use to attempt to contact an investigator as part of due diligence. The examples provided include by e-mail and registered letter. The guidance provides suggestions

and does not mean that a sponsor must contact clinical investigators by e-mail or registered letter.

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 22, 2014 9:43 AM
To: OC GCP Questions
Subject: Financial Disclosure Follow Up

I've got a question about what would be acceptable to the FDA in terms of covering the responsibility to obtain financial disclosure information through the required reporting period.

The beginning of a study seems straightforward enough. My question concerns the end of the study and the one-year follow up period.

I'm not clear on the guidance about "reminding" the investigators. When would that reminding take place?

Would collecting updated financial disclosure information at the close-out visit and reminding investigators of their obligation to inform us of any changes within the one year after the completion of the study (documenting that requirement on the disclosure form they sign as well as in the body of the visit report and follow-up letter) be adequate?

Or would the expectation be that we track them down and remind them of the requirement at the time of the one-year post study timepoint?

Thanks,
[Redacted]