

From: OC GCP Questions
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Financial Disclosure Update at Sponsor Change
Date: Wednesday, July 22, 2015 8:18:00 AM

Dear [REDACTED]

FDA's regulations and guidance use the term "promptly" in relation to 21 CFR 54, but, as you note, the time frame is not defined. As the new sponsor, you may want to consider sending a reminder to the investigators to remind them that they should update their financial disclosure information, if necessary, due to the change of sponsor, and submit any changes to you. This would also allow you, as the new sponsor, to take any action necessary to minimize bias for the remainder of the study, based on the updates received. In this way, you can show "due diligence" in ensuring that you obtained any financial disclosure information related to the sponsorship change. You could then do a more formal financial disclosure update at the end of the study, as you had planned to do.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov.

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration
Tel: 301-796-6563; Fax: 301-847-8640
Email: sheila.brown@fda.hhs.gov

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From: [REDACTED]
Sent: Saturday, July 18, 2015 8:38 PM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Financial Disclosure Update at Sponsor Change

Dear Sirs,

Our company, [REDACTED], has recently acquired another company that has an ongoing clinical study.

The FDA Guidance Document on Financial Disclosure states the following:

"Agency regulations require that an IND/IDE sponsor collect financial information from all clinical investigators and that clinical investigators promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study.

Therefore, if the study sponsor changes during the course of the study, the clinical investigators will need to update their financial disclosure information relevant to the new sponsor.”

I am wondering what time frame is considered to be “prompt” to collect the financial disclosure form after the sponsor change?

[Redacted]'s procedure requires collecting the updated financial disclosure form before PMA submission, and we are planning to file a PMA-S around this time next year. Therefore, we are going to collect the updated financial disclosure forms in early next year to prepare Form FDA 3454 and 3455. My question is this: is collecting forms in early next year too late to be considered “prompt” for sponsor change update?

It usually takes us about 3-4 months to collect the forms from all investigators including the due diligence effort to contact the investigators who left the study sites. Therefore, if we request the updated financial disclosure now, by the time we complete collecting the forms, we need to request the update again. We can avoid repeated requests of update of financial disclosure if FDA considers “prompt” when we request the forms in early next year. Please advise.

[REDACTED]