

From: OC GCP Questions
Sent: Monday, February 23, 2015 9:55 AM
To: [REDACTED]
Subject: RE: Financial Disclosure Question - FDA Form 3455

Dear [REDACTED]:

The February 2, 1999 date is the date that the regulations under 21 CFR 54 (including all reporting requirements) went into effect. Please refer to the preamble to the rule which was published on February 2,

1998: <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119145.htm>.

The December 31, 2015 date on the FDA Form 3455 is an OMB form expiration date. The form date reflects OMB (Office of Management and Budget) approval of the form as an FDA form that meets the requirements of the Paperwork Reduction Act. This date does not reflect financial reporting requirements.

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/RepliestoInquiriesToFDAonGoodClinicalPractice/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: Monday, February 16, 2015 11:22 AM
To: OC GCP Questions
Subject: Financial Disclosure Question - FDA Form 3455

Dear Sir or Madam:

There are conflicting requirements for financial disclosure between FDA Form 3455, and CFR and Guidance Document. The second item in FDA Form 3455 requires disclosure of any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation on the form of equipment, retainer for ongoing consultation,

or honoraria. 21CFR54.2 and 2013 Guidance Document require disclosure of any significant payments during the time the clinical investigator is carrying out the study and for 1 year following the completion of the study.”

While investigating this issue, I found the attached Q&A in FDA website. From this explanation, it is clear to me that the second item in FDA Form 3455 is not correct for the studies started after February 2, 1999. I also notice that FDA Form 3455 has an expiration date of December 31, 2015. Is it FDA’s intention to revise the form including the correction of the discrepancy of timeframe of significant payments disclosure requirement after December 31, 2015?

Thank you very much,

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