

From: OC GCP Questions
Sent: Tuesday, July 14, 2015 3:55 PM
To: [REDACTED]
Subject: RE: Financial Disclosure Collection

Dear [REDACTED]:

Sponsors are required to submit financial disclosure information for investigators who participate in covered clinical studies. The part 54 regulations define “covered clinical study” to mean “any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols and parallel track protocols.” (See 21 CFR § 54.2(e).) This definition includes clinical studies submitted in support of new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), abbreviated new drug applications (ANDAs) under section 505(j) of the FD&C Act, premarket notification submissions under section 510(k) of the FD&C Act, reclassification petitions under section 513 of the FD&C Act, premarket approval applications (PMAs) under section 515 of the FD&C Act, and biologics licensing applications (BLAs) submitted under section 351 of the Public Health Services Act (PHS Act), as well as studies submitted in support of amendments or supplements to any such applications. (See 21 CFR §§ 54.3 and 54.4(a).) Covered clinical studies would generally not include expanded access under section 561 of the FD&C Act.

There is a guidance on Financial Disclosure by Clinical Investigators which you might find useful:
<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.

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, July 07, 2015 3:20 PM
To: OC GCP Questions
Subject: Financial Disclosure Collection

Hi,

I am interested in understanding if there is a requirement to collect financial disclosure from new investigator's joining a study that has PMA approval and has surpassed 1-year after completion of the study?

Thanks in advance for your time!

Kind Regards,

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