

**From:** [OC GCP Questions](#)  
**To:** [Redacted]  
**Subject:** Question about financial disclosure form Investigators  
**Date:** Thursday, January 23, 2014 10:13:21 AM

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Good morning –

The answer is actually a little more complicated. The Form FDA 3455 and Form FDA 3454 are designed to be filled out by the sponsor/applicant, not by the clinical investigators. Clinical investigators are required to provide the sponsor with sufficient accurate information to allow subsequent disclosure or certification. The regulations do not specify how sponsors should collect this information, however, the FDA forms lack the background information necessary to allow clinical investigators to fill-out the forms.

You may want to review the FDA's guidance, "Financial Disclosure by Clinical Investigators" (available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>), specifically to section IV question/answer C.7 and the appendix.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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Office of Good Clinical Practice  
Office of the Commissioner, FDA

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.

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**From:** [Redacted]  
**Sent:** Tuesday, January 21, 2014 11:29 AM  
**To:** OC GCP Questions  
**Subject:** Question about financial disclosure form Investigators

Dear Sir/Madam,

I work for a Sponsor company and we are in the process of collecting financial disclosure forms from all Investigators that are participating on a Phase III study with us. Some investigators submit form 3455 and do not select any of the bullets, certifying that they do not have any financial interests. Is this sufficient or do they also need to complete form 3454? I greatly appreciate your guidance on this matter.

Warm regards,

[Redacted]