

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: disclosures
Date: Tuesday, October 13, 2020 11:30:00 AM

Good morning -

Thank you for your inquiry. A conflict of interest in a clinical trial related to a clinical investigator may be considered a conflict between the private interests and official responsibilities of the clinical investigator and the objective design, conduct and reporting of the clinical trial. A risk of such interests is that they may lead to intentional or unintentional bias or errors in the clinical trial and may compromise the well-being of the human research subjects.

FDA believes that the IRB or the institution should determine what constitutes a conflicting interest. The regulations at part 54 address different disclosure amounts--but amount above those indicated do not necessarily represent a "conflict of interest", rather they are amounts that need to be disclosed because they may be a source of "bias" in clinical trials.

You may be interested in the U.S. Department of Health and Human Services (HHS) guidance document, "Financial Relationships and Interests in Research Involving Human Subjects" (available at www.hhs.gov/ohrp/policy/fguid.pdf), which raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and, if so, what actions could be considered to protect those subjects.

You should check with your local and national laws and institutional internal policies and procedures to see if there are any requirements related to conflict of interest and clinical trials. The U.S. has regulations related to federally funded studies and ensuring objectivity ("Responsibility of Applicants for Promoting Objectivity in Research for which Funding is Sought" and "Responsible Prospective Contractors" available at www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

For studies that will be submitted to FDA to support marketing applications, there are requirements that clinical investigators report their financial interests and arrangements to the study sponsor (see 21 CFR part 54, Financial Disclosure (FD) by Clinical Investigators, available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1). The clinical investigator financial disclosure information, along with the steps taken to minimize bias in the study, is submitted to FDA in a marketing application supported by the clinical trial and is used in the evaluation of the conduct of the study and the integrity of the study data.

Please also see FDA's guidance on FD by Clinical Investigators. -- <https://www.fda.gov/media/85293/download>

Kind regards,

Doreen M. Kezer, MSN
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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.

-----Original Message-----

From: [REDACTED]
Sent: Tuesday, October 13, 2020 9:10 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: disclosures

Good Morning,

I am an employee of a hospital which is being offered to be paid by a Pharma sponsor to conduct a study. I am not receiving any Money, bonuses, financial incentives to assist as the investigator. Do I need to report this as a conflict of interest or in some other manner,

Thank you.