

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Research Pharmacist Serving on IRB
Date: Tuesday, February 26, 2019 10:54:00 AM
Attachments: [REDACTED]

Good morning –

The FDA regulations regarding IRB membership can be found at 21 CFR 56.107. In addition to describing the composition of the IRB membership, the regulations also state that no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The FDA regulations do not define what constitutes an IRB member conflict of interest, so many IRBs consider the current guidance on this issue and address this issue in their IRB written procedures.

I recommend that you determine, in accordance with the IRB's written procedures, whether you as the research pharmacist has conflict of interest, keeping in mind that an IRB member who is determined to have a conflict of interest may not vote or count towards quorum on that project. This may require discussion with appropriate facility representatives, including legal counsel and/or a COI committee, as applicable. You may also wish to review the joint HHS/FDA guidance, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, for additional information on conflicts of interest. The guidance can be found at [Financial Conflict of Interest: HHS Guidance \(2004\) | HHS.gov](#).

You may also wish to review FDA's guidance on IRB Written Procedures. [Search for FDA Guidance Documents > Institutional Review Board \(IRB\) Written Procedures](#)

FDA recommends that IRB members with a conflicting interest in a project recuse themselves by leaving the meeting room when the IRB conducts review of that project, except when requested by the IRB to be present to provide information. Any IRB member recusal should be noted in the minutes of the IRB meeting when recording votes on that IRB action.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
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.

From: [REDACTED]
Sent: Tuesday, February 26, 2019 4:11 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Research Pharmacist Serving on IRB

Greetings,

I would like to clarify the following:

I am the Investigational Drug Services (IDS) pharmacist at my institution, I am usually delegated to be the research pharmacist on all of the investigational drug studies run at our site.

I am also a voting IRB member in the same site. Lately, I have been questioned a lot by many sponsors being a voting IRB member in the studies they run at our institution considering a possible COI.

My question is : Does the nature of my role on the study affect the potential COI? Meaning, if the pharmacist is merely dispensing investigational drugs and has no responsibility for preparing the test article or evaluating or reporting data relative to the study activities, does this affect his/her role as a voting member of the IRB?

Do you have any written document that I can submit to sponsors when they question this.

Best regards,,

