

From: [OC GCP Questions](#)
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: request for clarification
Date: Tuesday, February 05, 2019 10:37:00 AM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your question, and for your patience in our delayed response given the government shutdown.

As you know, FDA's regulations at 21 CFR 56.107 describe the IRB membership requirements, including possessing the professional competence necessary to review the specific research activities and including at least one member whose primary concerns are in the scientific area. Although these regulations require the IRB membership to possess professional competence and to include at least one scientific member, the regulations do not specifically require that individual to be a physician.

In the preamble to the 1981 IRB regulations, in comment 55, FDA wrote *"FDA recognizes that it cannot specify in detail the composition of an IRB that would be appropriate to review each of the diverse types of studies that are included within FDA jurisdiction."* Comment 55 also notes that FDA *"...would expect that an IRB that reviews investigational new drug studies will include at least one physician."* In comment 58, FDA notes *"...an IRB must retain the necessary expertise to effectively review any protocol submitted to it, and therefore, it may need a number of scientists (whether medical doctors, dentists, technical staff, or others) on the IRB."* (46 FR 8958, January 27, 1981 - See <https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118296.htm>).

Therefore, if an IRB regularly reviews biomedical research (e.g., investigational new drug studies), FDA would expect that the IRB include one or more physician members with appropriate expertise relevant to the types of clinical trials reviewed, in order to assure that risks to subjects are minimized. An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise in addition to that available on the IRB. For example, although an IRB may have a family practitioner member, the IRB may invite a pediatric oncologist to its discussion of research studying a cancer drug in a pediatric population.

Utilizing a primary reviewer(s) system is not addressed in the IRB membership regulations. When the regulations are silent, IRBs, institutions, sponsors and investigators are free to develop procedures and practices that best suit their needs, as long as applicable regulatory requirements are met. IRBs are encouraged to utilize the flexibilities in the regulations in order to meet the needs of the particular research they encounter.

FDA's guidance titled, *"Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs"* (see <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM512761.pdf>) recommends that IRBs include a description of the reviewer system utilized by the convened IRB (e.g., primary reviewer(s)) along with a description of the documents routinely distributed to all IRB members and those that may be distributed to specific IRB members (e.g., primary reviewer(s)).

We are aware that some institutions, [REDACTED] may choose to utilize a primary reviewer system and choose to require a physician be assigned as a primary reviewer for an FDA-regulated study. Institutions/IRBs should describe any such requirements as part of their institutional/IRB written procedures.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner



From: [REDACTED]
Sent: Tuesday, January 15, 2019 4:20 PM
To: Donnelly, Janet <Janet.Donnelly@fda.hhs.gov>
Cc: [REDACTED]
Subject: request for clarification

We have a request from [REDACTED] for clarification about FDA guidance about physicians and other “clinically relevant” reviewing FDA-regulated research. The organization assigns physicians to review FDA-regulated research, but has asked whether a PharmD, or an RPh with a masters of science in hospital pharmacy could substitute for a physician when reviewing studies involving investigational drugs (this question does not apply to investigational medical devices – they would use a physician for that) Staff at the organization are uncomfortable with having a non-physician serve as the primary reviewer, but the pharmacists on the IRB feel they are qualified.

[REDACTED]
[REDACTED]

[REDACTED]