From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 3:38 PM
To: [Redacted]
Subject: RE: Physician Membership on IRB
Dear [Redacted],

In response to your email (below), let me give you the regulatory basis for requiring a physician on an IRB that reviews investigational drug studies.

FDA's regulations at 21 CFR 56.107 describe the IRB membership requirements. These include: (a)...possessing the professional competence necessary to review the specific research activities..., and (c) ...including at least one member whose primary concerns are in the scientific area. In the preamble to the 1981 IRB regulations, in comment 55, FDA wrote that it "...would expect that an IRB that reviews investigational new drug studies will include at least one physician." In comment 58, it 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." See 46 FR 8958 at 8966, January 27, 1981.

I hope this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [Redacted]
Sent: Saturday, August 27, 2005 10:21 AM
To: gcpquestions@oc.fda.gov
Subject: Physician Membership on IRB
Dear GCP Program:

I see in the FDA Information Sheets (the IRB self-evaluation checklist) that a physician member on the IRB is expected when an FDA-regulated investigational product is the the subject of the research review, but I have not been able to find a specific regulation that requires the physician. Below is the Checklist language.

Item IX E. Voting requirements30 _____- quorum required to transact business _____- diversity requirements of quorum (for example requiring at least one physician member when reviewing studies of FDA regulated articles)_____- percent needed to approve or disapprove a study _____- full voting rights of all reviewing members_____- no proxy votes (written or telephone) _____- prohibition against conflict-of-interest voting

As you know, the IRB membership regulation stipulates only that one member must be scientific. Can you please explain to me if this requirement for a physician member is an enforced FDA policy and on what regulatory basis that enforcement would be applied? How would FDA regard the lack of a physician member in the review of an FDA-regulated article? I have seen one warning letter [Redacted] where the lack of a physician member was mentioned (by CBER) but that was in 2003. The statement from the warning letter is below, and it implies that it is acceptable not to have a physician as part of the voting membership, provided the IRB has procedures to account for it. I'm not sure what that means and how that would be solved.

F. IRB written procedures should describe how the IRB will review proposed research and continuing review of previously approved research when the only IRB physician member is not documented as present or there is no record of the physician's vote, as occurred on November 11, 1997 and May 5, 1999.

Thanks very much and I really appreciate your reply. I thought I once saw an FDA regulation that required a physician to be on the IRB when FDA-regulated products are reviewed, but I can't remember where that was.

[Redacted]