From: Lepay, David
Sent: Friday, April 23, 2004 3:58 PM
To: **[Redacted]**
Cc: Lee, Bonnie
Subject: RE: question regarding review of IND protocols
Dear **[Redacted]** ,

[Redacted]

In your e-mail, you asked whether a physician would need to be present at an IRB meeting for an investigational drug protocol to be acted upon by the IRB. I've discussed this with Bonnie Lee (Associate Director for Human Subject Protection Policy in my office), and our shared opinion is as follows:

The only quorum requirement contained in the IRB regulations is at 21 CFR 56.108(c). This states that research that is reviewed at a convened meeting must have "...a majority of the members of the IRB...present, including at least one member whose primary concerns are in nonscientific areas." Thus, although FDA might assume that an IRB that reviews investigational new drug studies will include at least one physician, FDA does not explicitly require a physician to be present for the IRB to conduct business (see one exception, below). That being said, however, 21 CFR 56.107(a) states that the IRB "...shall be sufficiently qualified through the experience and expertise of its members...to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of...professional conduct and practice." Thus, it seems reasonable to assume that in most instances you would need the expertise provided by a physician in reaching a decision on the approvability of a protocol involving an investigational drug product.

Under FDA's emergency research regulations, the presence of a licensed physician <u>is</u> required. See 21 CFR 50.24. In that case, the IRB (with the concurrence of "a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation") needs to find and document that the criteria for waiving informed consent have been met. 21 CFR 50.24(a). Thus, such a physician would need to be present at the convened meeting to consider and approve a protocol involving emergency research subject to 21 CFR 50.24.

We do not believe that FDA has ever taken a position on the various licenses given to physicians. It is up to the IRB and its institution to determine that the individual is qualified to serve on the IRB and makes a positive contribution to its diversity and activities.

I hope these thoughts are helpful to you.

My best, Dave

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Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US 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: Thursday, April 22, 2004 5:23 PM
To: david.lepay@fda.hhs.gov
Subject: question regarding review of IND protocols

Dr. Lepay,

I enjoyed your presentation earlier this week and the opportunity to meet with you. I have a question regarding protocols using investigational drugs. In order for a protocol to be voted on at an IRB meeting must there be a MD present if the protocol contains an investigational drug. If the answer is yes, would a PharmD suffice in lieu of an MD? Would a Doctor of Chiropractic suffice in lieu of an MD? Would a DO suffice as well?

I appreciate any information you can provide.

[Redacted]