**From:** Lee, Bonnie on behalf of OC GCP Questions
**Sent:** Monday, April 26, 2004 12:00 PM
**To:** **[Redacted]**
**Subject:** RE: IRB Membership and designation of Scientist/Non-scientist

Dear **[Redacted]** ,

While it sounds as though this individual would be an asset to the IRB, from your description I would designate the person as a scientist. This would be based on the member's education and work experience. Even though the person is no longer working in a scientific area that does not mean the person would not approach various issues from a scientific perspective--particularly with the individual's 20 year experience in working in a scientific field. I think that you really need to include some other individual who is nonscientific in training and work experience to fulfill the position of your nonscientific member. 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

-----Original Message-----
**From:** **[Redacted]**
**Sent:** Tuesday, April 20, 2004 11:12 AM
**To:** gcpquestions@oc.fda.gov
**Cc:** **[Redacted]**
**Subject:** IRB Membership and designation of Scientist/Non-scientist
**Importance:** High

Hello,
I need clarification on the FDA's policy for the designation of an IRB member to be scientific or non-scientific. We have a member who has a BS in Medical Technology (**[Redacted]** ) and worked in the scientific field as a Medical Laboratory Technologist and Medical Data Scientist **[Redacted]**. From 1995 to present this member has had a non-scientific focus and is a copy-editor and freelance writer, much of which is for children's publications.

The person's primary concerns are now in the non-scientific area (per 21 CFR 56.107(c)) and have been non-scientific since joining the IRB, but this person is not unambiguously non-scientific (which is stated in the FDA Information sheets, question 17). Would you expect to see this person designated as a scientist or non-scientist?

Your clarification and guidance is greatly appreciated!
Kind regards,
**[Redacted]**