

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Scientific/Non-Scientific  
**Date:** Friday, April 03, 2015 12:52:43 PM

---

Good afternoon –

This is not a black and white answer as I don't know the composition of your IRB so I wanted to check with my colleagues before responding as I remembered we had discussed this in the past. For a specific degree we would say:

A person who is trained and working in a setting relevant to their subject matter expertise (science-based) would likely be more of a scientist than a non-scientist. This becomes even more important if the IRB in question is relying on this person to be the ONLY non-scientist on this particular IRB.

There are several places where who could be considered a non-scientific member of an IRB is discussed.

•In the preamble to the medical device Final Rule, "Procedures for Investigational Device Exemptions" (January 18, 1980), p. 3748, comment 111 states:

"...For purposes of this regulation, a social scientist is considered to be an individual whose primary activities are in a nonscientific field. Thus a social scientist may serve as a lay member on an IRB."

OHRP also has some guidance:

In an FAQ found electronically at <http://answers.hhs.gov/ohrp/categories/1565>. (Copied is only the response relevant to the scientist/nonscientist person. There is further discussion regarding other members.)

How do I determine the various categories of members for the IRB roster?

The following are some general guidelines to assist you in composing the IRB membership roster. Scientist/Nonscientist - Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

There is also an excellent YouTube Video accessible from the OHRP website on IRB membership that includes a discussion as to who can be considered a non-scientist. It can be accessed from <http://www.hhs.gov/ohrp/policy/institutions/index.html> (OHRP: IRB Membership).

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) if 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:** Thursday, April 02, 2015 4:23 PM  
**To:** OC GCP Questions  
**Subject:** Scientific/Non-Scientific

Greetings,

There seems to be a difference of opinion for one of our board members regarding their status (Scientific/Non-Scientific). Based on the CV (attached), what would FDA consider this member to serve as a scientific or non-scientific member?

Your assistance is greatly appreciated.

Sincerely,

[REDACTED]