

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Scientific v. Non-Scientific Designation for those with ambiguous backgrounds
Date: Monday, May 09, 2016 12:41:09 PM
Attachments: [REDACTED]

Good morning –

FDA generally does not review internal SOPs. However, please see earlier emails that have addressed this issue previously. I believe the issue can be explained this way.

- If a member has a science degree but has never worked in the science field, FDA would consider this member to be non-scientific.
- If a member has a science degree or background and has worked in the science field, FDA would consider this member to be scientific as this member's previous work experience might approach various issues from a scientific perspective.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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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: Monday, May 09, 2016 9:42 AM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Scientific v. Non-Scientific Designation for those with ambiguous backgrounds

21 CFR 56.107(c) requires that each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in

nonscientific areas. However, the term nonscientific is not defined in the regulations. In reading FAQs from the FDA and OHRP, it seems FDA is taking a more strict approach to defining members as scientific when they have ambiguous backgrounds. We hear recent FDA audits have discussed with IRBs that member with ambiguous backgrounds, such as a lawyer with a Bachelors in Science, should be categorized as scientific even though the member is not active in the scientific field nor would necessarily view scientific activities from a scientific standpoint.

FDA FAQ

FDA believes the intent of the requirement for diversity of disciplines was to include members who had little or no scientific or medical training or experience. Therefore, nurses, pharmacists and other biomedical health professionals should not be regarded to have 'primary concerns in the non-scientific area.' In the past, lawyers, clergy and ethicists have been cited as examples of persons whose primary concerns would be in non-scientific areas. Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. While such members are of great value to an IRB, other members who are unambiguously non-scientific should be appointed to satisfy the non-scientist requirement.

Food and Drug Administration, Guidance for Institutional Review Boards and Clinical Investigators, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm>

OHRP FAQ

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.

Office for Human Research Protections, DHHS, IRB Registration Process, available at <http://answers.hhs.gov/ohrp/categories/1565>

We are looking at our SOPs to be more precise in our definitions, including properly categorizing those members with ambiguous backgrounds.

A. Scientific v. Non-Scientific

1. Each member is classified as either "scientific" or "non-scientific" based upon a review of his/her curriculum vitae (CV), or equivalent documentation of education, training and education, specialization, professional certifications, and work experience.
2. Scientific Member. 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. A scientific member is a member whose primary educational background and experience is in a scientific field. Examples include physicians, Ph.D. level physical or biological scientists, nurses, or other biomedical health

professionals.

3. Non-scientific Member. 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. A non-scientific member is a member whose primary educational background and experience is not in a scientific field. Examples include lawyers, ethicist, teacher, homemaker.

4. Ambiguous backgrounds

a. Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. or a non-scientific professional whose bachelor's degree is in science.

b. When an individual is still active in both discipline areas, the member should be designated as scientific.

c. When the individual has demonstrated an intended career change from a scientific field to a non-scientific field and their current training and occupation would incline them to view submissions from the standpoint outside the scientific discipline, then the member can be designated as non-scientific. For example, a lawyer whose bachelor's degree was in a scientific field, but the individual has not worked, nor kept up-to-date or involved professionally in the scientific field, could be considered a non-scientific member.

Questions:

A. Would FDA ever view someone with an ambiguous background to be appropriately categorized as non-scientific?

B. If yes, does the draft SOP above provide a satisfactory method to appropriately categorize IRB members with an ambiguous background as scientific or non-scientific?

Best regards,

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]