Institutional review boards (IRBs) are responsible for protecting the safety, rights and welfare of human subjects in clinical research. The regulations — and common sense — dictate that experience, expertise and diversity of the members are important attributes of an effective IRB. Research institutions can draw on a large pool of physicians and other scientists to fill most of the Board seats, but what about “Community Members”? What, exactly, is a Community Member? What are their responsibilities? Where can they be found? How should they be trained? How do you keep them once you have them?

What is a “Community Member”?
Many people are surprised to learn that federal regulations do not mention “community members” per se. Instead, they say (boldface added):

- The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes... (45 CFR 46.106(a) and 21 CFR 56.106(a))
- Each IRB shall include at least one member whose primary concerns are in scientific areas and **at least one member whose primary concerns are in nonscientific areas.** (45 CFR 46.106(c) and 21 CFR 56.106(c))
- (d) Each IRB shall include **at least one member who is not otherwise affiliated with the institution** and who is not part of the immediate family of a person who is affiliated with the institution. (45 CFR 46.106(d) and 21 CFR 56.106(d))

The regulations refer to a non-scientific member and an unaffiliated member. The same person — an unaffiliated lay person usually referred to as the “Community Member” — often fills both roles. He or she is not meant to “represent” the community or any particular segment of the community. In fact, the regulations do not mention “representation” at all. In the event that a particular group of subjects warrants extra protection, the regulations state:

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. (45 CFR 46.106(a) and 21 CFR 56.106(a))

In summary, “Community Member” is a label used to describe IRB members who serve in a nonscientific or unaffiliated capacity. Two different people may play these roles, or one person may wear both hats. This nonscientific and/or unaffiliated IRB member is not intended to represent a particular category of subjects.

Community Member Responsibilities
Within the limits of their expertise, Community Members have the same responsibilities as any other IRB member. They also have the following responsibilities:

- Provide non-biased opinion in relation to the institute.
• Provide the voice of the participant in the research process.
• Provide balance to pro-research viewpoint.
• Provide unique viewpoint not biased by employment.
• Provide values of the community, neighborhood, patients, public and society to the research process.

Community Members should not be limited to evaluating consent forms or the “easy” parts of a protocol. Their vote has the same weight as those of the physicians and scientists at the table. It is interesting to note the regulatory requirement for the presence of a nonscientist (who may or may not be unaffiliated) for the establishment of quorum:

In order to fulfill the requirements of this policy each IRB shall... review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. (45 CFR 46.108 and 21 CFR 56.108)

Who is a “Non-Scientist”?
The regulations do not state how to determine who is a scientist or non-scientist for purposes of IRB membership. However, OHRP, in its “Registration of an Institutional Review Board (IRB)” form, states:

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.

FDA, in its “Guidance for Institutional Review Boards and Clinical Investigators,” states

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.

Thus, according to these guidances, orderlies, attorneys and florists qualify as non-scientists. Physicians, pharmacologists and medical researchers do not qualify. Nurses, lab technicians, and members of other allied medical professions may qualify, depending on their training, experience, job responsibilities, and perspectives. OHRP considers a chemist without biomedical research training to be a non-scientist member, but FDA does not.

Where to Find Community Members
Good places to look for Community Members are local chapters of the American Cancer Society and the Wellness Community; churches; PTAs; service organizations like the Lions, Elks, Rotary, Kiwanis and Optimist Clubs; disease-specific support groups; previous
research subjects and their family members or caregivers; and local junior colleges and universities.

Retired persons can make good IRB members. Retired physicians, bench scientists, and educators might be excellent choices. Current Community Members might recommend friends and neighbors. An afternoon of intellectual discourse, even in such an arcane area as clinical research, has great drawing power for many people.

**Educating Community Members**

Imagine attending a family reunion of distant relatives at which everyone is speaking an obscure Greek dialect. They welcome you, ask you to take a seat, and then go back to visiting with their cousins. You are totally lost. This is what a clinical research IRB meeting must feel like to many new Community Members. Phase I, double blind, placebo control, crossover, Belmont Report, etc., are terms seldom heard by the average person. While a physician unfamiliar with clinical research can draw on a base of relevant knowledge, a non-scientist Community Member does not have that advantage.

A robust orientation and continuing education program can provide Community Members with the knowledge to be fully functioning IRB members and thus meet the spirit of the law and not just the letter.

Orientation of a new IRB member should cover how IRBs protect research subjects, the regulations, and ethical standards of clinical research. It should also include the administrative aspects of IRB operation, such as the following:

- Meeting times and locations
- Expectations of reviewers
- How reviews are assigned
- Voting procedures
- Conflict-of-interest policies
- IRB office organization
- The IRB website and available resources for members
- How to use the electronic IRB system
- Continuing education

An educational program that covers basic clinical research topics for Community Members provides them with the essential knowledge and jargon they need to participate fully at meetings. In other words, it should enable the Community Members to translate from ancient Greek to modern English. Suggested topics to cover are:

- Why IRBs Do What They Do
- An Introduction to Clinical Research Studies
- The Consent Process
- Vulnerable Population Protections
- Drug Development & INDs
- What is an IDE?
- DSMBs and Monitoring Plans
- Foreign Language Consents
- Pregnant Women in Research

Monthly presentations are another way to provide training opportunities on a variety of timely topics. One of our institutions videotapes these monthly seminars and posts them in
a password-protected section of its website, along with .pdf copies of the PowerPoint slides. The website also houses prior workshop materials, handouts from the 10-minute educational presentations at each IRB meeting, and other resources.

A monthly, informal drop-in help session provides a chance for IRB Members to have individual questions answered. Help sessions should be held at a set time each month. It is easier for members to attend at lunch time, especially if lunch or drinks and cookies are provided. A mentoring program for all new IRB members accelerates the learning process. One good exercise is for new members to present a practice review to their mentor. They can then compare it to the real review presented at the IRB meeting. A survey of all Duke IRB members revealed that those who had been mentored became comfortable in their IRB role in about six months versus 12 months for those who had not.

And finally, offering an annual half-day symposium with outside speakers provides an in-depth training opportunity. By limiting the symposium to only IRB Members, the presentation can focus on issues and challenges unique to IRB Members.

Retention of Community Members

The foundations of retention are respect and appreciation. If they do not deserve respect for their intelligence, thoughtfulness and diligence, they should not be on the IRB. Most new Community Members feel like outsiders, so the IRB Chair should take the lead in actively soliciting their input. Community Members should not be treated as “silent partners.”

In Texas, there is a Community Member network for all Texas Medical Center institutions: 13 hospitals, two medical schools, three nursing schools, a school of public health, and several graduate schools. The Network hosts a quarterly luncheon in Houston with a speaker on a topic of interest and the opportunity to share experiences. Participation helps Community Members feel supported and empowered.

Community Members normally receive reimbursement for out-of-pocket expenses. Other ways to show appreciation, respect and support for Community Members include:

- Conduct IRB meetings in a professional and collegial manner that shows respect for all participants.
- At IRB meetings, explicitly mention their accomplishments and distinctions, such as shepherding a congregation or teaching thousands of students over the years.
- Give certificates for milestones like presenting their first protocol review and going beyond the minimum requirements, e.g., attending the PRIM&R Community Member track.
- Give token gifts, certificates, and pins on service anniversaries.
- Give institutional perquisites like library access, free parking, private tours, and tickets to cultural events as the institution.
- Give them the opportunity to make the first comment about a protocol, to set the community context.
- Some IRBs offer their committee members annual stipends or per-meeting honorariums. In some cases, the stipends are the same for all members, scientific and nonscientific. In other cases, only unaffiliated members are offered remuneration.

Conclusion

The non-scientific and unaffiliated IRB member is more than a regulatory requirement or bureaucratic headache. The Community Member is usually the one member at the IRB table
with perspectives unfettered by an institutional affiliation. They often see the trees other members, too far into the scientific forest, miss. Clinical research delves into the unknown; to minimize the risks to research subjects, we need the expertise, experience and perspective of each and every IRB member. While the Belmont principles of respect for persons, beneficence and justice apply to study subjects, they are worthy guidelines for working with community and other IRB members as well.

Reference


Note

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