

Solving the IRB "Community Member" Problem

By Charlotte Coley

Recruiting and retaining members for a clinical institutional review board (IRB) can be a challenge, especially for unaffiliated, non-scientist members. Imagine you are a retired school teacher, engineer or Realtor who is interested in IRB membership as intellectually stimulating community service. Then imagine coming up to speed on terms like "double-blind placebo-controlled cross over study," "therapeutic misconception," and "investigator's brochure." Would you be motivated to dig in or run far away? Now imagine that you have joined an IRB. The other members greet you pleasantly, but they have advanced degrees, some are wearing white coats, and the conversation is about medicine and internal institutional matters. You have been invited to join this group specifically because you are not one of them. How will you ever feel competent reviewing clinical research studies and contributing to the discussion?

This article will discuss an approach to attracting such people to IRBs and solving the "community member" problem.

IRB Composition

Federal regulations specify the composition of institutional review boards (IRBs):

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, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects... 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... 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 46.107 and 21 CFR 56.107)

Except when an expedited review procedure is used..., [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)

Many IRBs comply with these regulations by creating boards that consist of affiliated physicians, pharmacologists and other scientists and health professionals, plus one member from the community who is both unaffiliated and a non-scientist. The "community" member becomes the designated community representative, relieving the other members of such concerns.

However, the regulations do not assign "consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes" to one "community member." There is no requirement that the community member be a non-scientist or even be more sensitive to community attitudes than any other member. All members share responsibility for the community, and one could argue that explicitly assigning that responsibility to a single member violates the spirit of the regulations. Further, there is no requirement for a non-scientist on the IRB, just a member "whose primary concerns are in nonscientific areas."

Use of the traditional community member role limits the options for board membership. The regulatory requirements for board membership are:

- At least one member whose primary concerns are nonscientific and is present to meet quorum requirements (except for expedited reviews).
- At least one member whose primary concerns are scientific.
- At least one unaffiliated member.
- The IRB as a whole is "sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects."

Regardless of the composition of the IRB, the manner in which it meets these requirements should be documented.

A New Membership Category

Until six years ago, the policy at my institution was to staff IRBs with one member from each of 18 clinical departments, plus someone from the theology department and a community member. However, as the number of clinical IRBs grew to eight, a shortage arose of qualified and interested people.

On the other hand, we had to turn away potential members from these categories:

- Affiliated scientists and non-scientists
- Unaffiliated scientists, especially retired professionals

To solve these problems, we created a category of "collocative" IRB members that consists of people who are in any of the four combinations: affiliated scientist, affiliated non-scientist, unaffiliated scientist, and unaffiliated non-scientist (the traditional community member). Rather than calling this category "miscellaneous" or "other," we settled on the term "collocative," which the Oxford English Dictionary defines as "the act of...placing together with, or side by side with, something else."

Some of our current and former collocative members include the following:

- Chair of the Department of Statistics (retired)
- Film critic (retired)
- Florist (retired)
- Headmaster (retired) with degrees in divinity and social work
- Hispanic telecommunications company vice president (retired)
- Hospital chaplain with a Ph.D. in pharmacology
- Hospital social worker
- Information Technology specialist with a Ph.D. in chemistry
- Mechanical engineer (retired)
- Music teacher (retired)
- Pharmacist (retired)
- Physician (retired)
- Public health professor (retired)
- Retired bishop
- Study coordinator with a Master's degree in Christian education

Orientation and Retention

All new IRB members participate as non-voting members during their first, observational meeting and do not serve as a primary reviewer until their third or fourth meeting. Like other members, collocative members receive introductory and continuing training.¹ They also can access a members-only website and participate in a monthly drop-in help session for one-on-one questions and answers. These programs reduce the anxiety of potential collocative members and help make them comfortable as full contributors.

The typical clinical IRB at our institution has 18 members, including three or four collocative members, typically two non-scientist members and at least one unaffiliated member. The presence of three or more collocative members means they do not feel like the "odd duck."

Retention of collocative members is very good, with typical service length on the IRB of three or more years. We recognize service longevity by giving IRB members certificates of appreciation and lapel pins on first, third and multiples of fifth year anniversaries.

Conclusion

Recruiting and retaining non-scientist and unaffiliated IRB members can be challenging, but the regulations allow flexibility in meeting the requirements. The concept of collocative members creates a larger, more capable, and more diverse pool of candidates.

Reference

1. "Recruiting, Educating and Retaining IRB Community Members," Gigi McMillan, Charlotte H. Coley, and Paula Knudson, *Journal of Clinical Research Best Practices*, June 2010.

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