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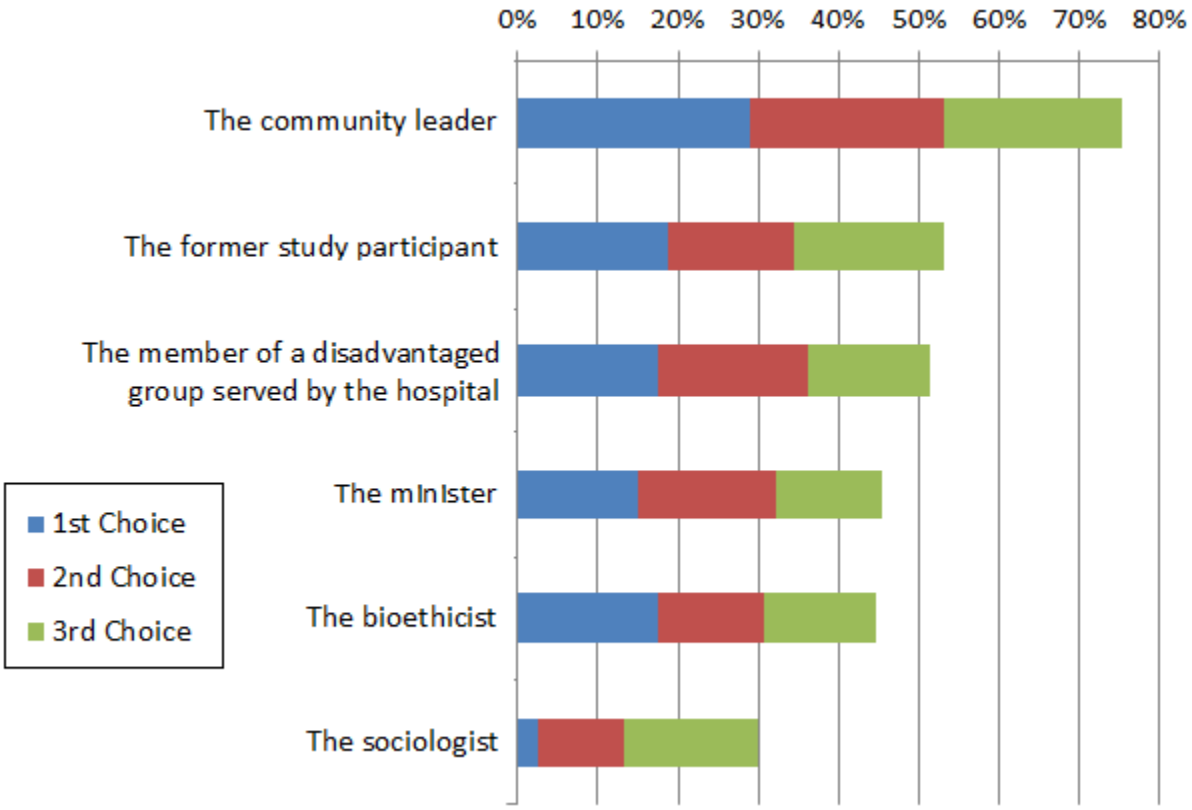
Clinical Research Ethics Question of the Month: Who Do You Invite to Join Your IRB?

By Norman M. Goldfarb

You are the director of human research protection at a community hospital. You have one IRB with seven members. Six of the members are physicians with staff privileges at your hospital. The seventh member, a representative from the community, just resigned from the IRB. Six qualified people have applied to fill the empty seat: a bioethicist, a minister, a former study participant, a community leader, a sociologist, and a member of a disadvantaged group served by the hospital. Because of a hospital policy that is set in stone, you can accept only one new IRB member. Which one do you choose? You have no other information to make your decision and no clever way to dodge it.

Results

Chart 1. Who do you choose invite to join your IRB?



The clear favorite (1st+2nd+3rd choice) of the 407 clinical research professionals that responded to the survey is the community leader (75% total). The former study participant (53%) edged out the member of a disadvantaged group served by the hospital (52%), closely followed by the minister (45%) and the bioethicist (45%). The sociologist was the least favored (30%). The first choices followed the same order, except for the minister, who fell from fourth to fifth place.

Respondents explained their choices with the following comments:

The community leader:

- Should be well-versed on community demographics, cultures, perspectives and priorities.
- Is likely loyal to the segment of the community he or she leads.
- Is likely to have a wide network of contacts from which to obtain input.
- Could help the community learn about clinical research.
- However, might be more interested in his or her own agenda.

The former study participant:

- Could address the realities of a clinical study, and have credibility on such matters.
- However, would need nerves of steel to challenge so many doctors.

The member of a disadvantaged group served by the hospital:

- Would most likely notice when the informed consent form is culturally inappropriate or not understandable to members of the community.
- Would be sensitive to issues of coercion and undue influence.
- Would most likely have different perspectives than those of the physicians.
- However, might be reluctant to counter the opinions of six physicians.

The minister:

- Would bring a high moral standard.
- Would likely have training in ethics.
- Would likely make the well being of the research participants the priority.
- Would likely have broad community experience with a variety of vulnerable populations.
- Would be the least likely to be considered scientific.

The bioethicist:

- Would care the most and know the most about ethical issues.
- Would have the training to think through the issues in an independent and objective manner.
- Would be able to negotiate a decision in the best interest of all parties.
- However, is a scientist.

The sociologist:

- Has studied widely divergent populations and their environments.

Discussion

U.S. federal regulations (21 CFR 56.107) state (italics added):

> (a) Each IRB shall have at least five members, *with varying backgrounds* to promote complete and adequate review of research activities commonly conducted by the institution. 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. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. 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 those subjects.

(c) 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*.

(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.

Any of the proposed new members would meet the "varying background," "diversity," and "not otherwise affiliated" *(i.e.,* "community") requirements*.* All the proposed members would meet the "nonscientific" requirement, probably including the bioethicist, who might be surprised to learn that he or she is a scientist.

Some proposed new members would probably meet the "sensitivity to such issues as community attitudes" better than others. The disadvantaged person, while perhaps not sensitive to a broad range of community attitudes, would be acutely sensitive to attitudes that might be foreign to the other board members.

While the regulations do not require or even recommend a member to speak for the community of previous study participants, this community certainly constitutes a very relevant part of the broader community.

Several respondents remarked on the lack of diversity in the current board membership, suggesting that the board should be expanded or depopulated to accommodate, perhaps, three new members. The exiting physicians and/or the unaccepted new members could become advisors to the board. (Do any IRBs have study participant advisory boards?) The interpersonal dynamics of a board comprised mostly of physicians might also be intimidating for a sole non-scientific community member.

Next Month's Question

You are the principal investigator/owner at an independent clinical research site that is struggling financially. The first person you enrolled in a cardiology study had a serious stroke after one week in the study. The person had no history of strokes or related conditions. After unblinding, your SAE report to the very large CRO identified the study drug as causation. After a heated discussion, the CRO's medical monitor says he will "overrule" your conclusion and report the SAE (on your behalf) to the IRB and FDA with unknown causation. To prevent further issues, the study will be closed at your site. Should you tell somebody about the situation?

Read the full question and give us *your* answer at:
https://www.surveymonkey.com/r/CWSP3JB

Please send your ethical conundrums to ngoldfarb@firstclinical.com.

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