Published in final edited form as:
J Empir Res Hum Res Ethics. 2012 February ; 7(1): 1–6. doi:10.1525/jer.2012.7.1.1.

The Participation of Community Members on Medical Institutional Review Boards

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Abstract

The goal of this study was to describe the contributions of community members (unaffiliated members) who serve on institutional review boards (IRBs) at large medical research centers and to compare their contributions to those of other IRB members. We observed and audiotaped 17 panel meetings attended by community members and interviewed 15 community members, as well as 152 other members and staff. The authors coded transcripts of the panel meetings and reviewed the interviews of the community members. Community members played a lesser role as designated reviewers than other members. They were infrequently primary reviewers and expressed hesitation about the role. As secondary or tertiary reviewers, they were less active participants than other members in those roles. Community members were more likely to focus on issues related to confidentiality when reviewing an application than other reviewers. When they were not designated reviewers, however, they played a markedly greater role and their discussion focused more on consent disclosures than other reviewers. They did not appear to represent the community so much as to provide a nonscientific view of the protocol and the consent form.

Keywords

IRB; community member; bioethics; research ethics

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All institutional review boards (IRBs) in the United States are required by federal regulation to include at least one person not affiliated with the institution (45 CFR 46.107d). Similar suggestions have come from international organizations such as the World Health Organization and the Council for International Organizations of Medical Sciences (Dresser, 2008). These members from outside the institution are officially known as "unaffiliated members" but often are referred to as "community members."

Although there are no federal guidelines regarding the specific role of community members, there are three views on the unique functions that community members may serve. First, as Veatch (1975) has argued, if community members are laypeople (which reflects the frequent confusion between the mandate for an unaffiliated member and the federal regulatory requirement that IRBs have "at least one member whose primary concerns are in nonscientific areas"(45 CFR 46.107c)), they can provide an ordinary person's perspective and will identify issues that professionals may miss. A second viewpoint is that community members will reflect local cultural mores, thus justifying the concept of local review (National Commission for the Protection of Human Subjects, 1978; Curran, 1969). A third view is implied by the term "unaffiliated." The community member might be seen as guarding community interests against the parochial interests of the institution. However, it is possible that none of these views are correct, and that community members are essentially indistinguishable from the other members of the committee.

Several surveys have described how community members see their roles. In a survey of 198 community members, Porter (1987) reported that nearly all participants strongly endorsed a variety of role responsibilities, including representing community attitudes, reviewing informed consent documents for completeness and clarity, acting as advocates for human subjects, and being sensitive to ethical issues relating to the proposed research. Sengupta and Lo (2003) found that the majority of 32 community members thought that their role was "to represent or give a voice to the 'community' of human subjects" and to simplify consent form language. In contrast, Anderson (2006) found that community members believed they had the same role as other IRB members.

At the same time, there has been considerable criticism of community representation on IRBs as well. Wallwork (2003) titled his article "Failed Community Representation: Does the Process Inhibit Full IRB Participation by Community Representatives?" Schuppli and Fraser (2007) reported that there were some impediments to the effectiveness of community members serving on Canadian research ethics boards, including a lack of unaffiliated people who were willing to serve as community members; community members who were friends or relatives of other committee members and thus not unbiased; and an intimidating atmosphere for community members at some ethics committees.

The goal of this paper is to determine what role community members play in IRB activities. In brief, are they community representatives, reflecting and defending local cultural mores; laypeople who assess research ethics issues as the common person would; unaffiliated independent guardians against institutional self-interest; some combination of these three or none of the above? To determine the actual role a community member plays in IRB meetings, we conducted an in-depth observational study of participants' discourse in IRB meetings and interviewed community and other members and staff of IRBs.

Methods

Data and Participants

We observed and recorded discussions among 216 IRB members and 47 staff at 20 IRB meetings (17 of which included community members present and consenting to participate

in our study) taking place at 10 academic medical centers. These sites were recruited from among the medical centers that were the 25 largest recipients of NIH funds in 2004. This focus of the study was chosen because large medical centers do much of the clinical research in the United States and because their IRBs should have sufficient resources to review protocols thoroughly. At each site, we studied two panels that reviewed general biomedical applications (i.e., excluding specialized panels such as those that reviewed only pediatric or transplant protocols). Between November 2006 and July 2009, we observed and audiotaped one meeting of each panel and, to ensure the most complete evaluation of protocols, only recorded and analyzed discussions of new or resubmitted proposals discussed at the meeting. Three panels were excluded from this analysis because a consenting community member was not present at the observed meeting. The median number of new or resubmitted proposals discussed at each meeting was 5 (range 3 to 10).

This study received IRB approval at each of the sites involved, as well as at the home institutions of the principal investigator and each co-investigator. All participants at the observed IRB meetings were asked for their written consent to be audiotaped and interviewed. From a total of 17 panels, 231 of 249 potential subjects provided their consent. The comments of IRB members who declined to participate were deleted from the data. Twenty-nine of the 249 potential participants who attended an observed IRB meeting were community members (three of whom attended both panel meetings at their site). Two community members did not consent and therefore did not have their statements transcribed. Fifteen of the 27 consenting community members agreed to be interviewed about their role on the IRB. In addition, six protocols were excluded from the data because a refusing participant was the primary reviewer of a protocol. Because reviews of protocols with nonconsenting primary reviewers were excluded, the exclusion of the statements of nonconsenters resulted in the exclusion of only 0.06% of speaking turns. In the 17 panels, we observed and recorded discussions of 77 new protocols and 16 previously deferred and subsequently resubmitted protocols (protocols that had previously been reviewed at a full board IRB meeting, but were determined to need another full board review because of the extent of revisions required), for a total of 93 protocols discussed by 179 reviewers. Table 1 presents data on the research focus and status of the 93 protocols. There were no significant differences in the type of member responsible for a protocol based on whether it was a new study or previously reviewed and resubmitted; therefore our analysis combines these two types of reviews. Further detail on the methods of the study is contained in Candilis et al. (in press).

Coding of Transcripts

Panel meetings were transcribed and then redacted of any information that would identify the site, the PI, or the protocol. A detailed codebook was developed on the basis of observations from a pilot study, and modified using data collected from the early sites (codebook available on request from the authors). Minor changes that were made during the early stages of coding led to recoding the transcripts that had previously been coded. Two coders separately coded the meetings and then compared results to resolve disagreements. Remaining disagreements were resolved by review with the first author.

Quantitative Analyses

In our analyses we examined the topics discussed and the frequency of participation by different categories of IRB members, using the counts of both speaking turns and the number of words in those speaking turns. However, because the findings for the number of words were essentially identical to those for speaking turns, we have only presented the analysis of speaking turns here. Since many speaking turns involve multiple topics, and

others were not pertinent to the topics with which we were concerned, the percentages of speaking turns do not sum to 100%.

Topic frequencies and speaker frequencies are presented as simple percentages of speaking turns per person per protocol. Because the data consisted of counts of speaking turns by topic spoken by each participant, and participants were grouped into IRBs, significance tests were conducted using mixed-models Poisson regression with participants and IRBs as random effects. The Poisson model assumes that the events in the counts were statistically independent, conditional on the covariates in the model. However, unmeasured variables associated with participants or IRBs may induce dependence among utterances. To counter this, we captured the dependence among utterances associated with unmeasured participant variation by including a random effect for participants. Similarly, the dependence associated with multiple participants grouped into an IRB was managed by including a random effect for IRBs. There is another potential source of dependence that this model cannot handle, which is serial correlation among utterances (Rabe-Hesketh & Skrondal, 2008). However, there is, to our knowledge, no suitable software that can handle both hierarchically structured samples and categorical time series data, so we did not attempt to address this. As a result, there may be additional dependence in the data, in violation of the assumptions of the Poisson model. Analyses were conducted using SAS version 9.2 and STATA version 11.2.

Qualitative Analyses

We reviewed the 15 community members' interview transcripts for descriptive purposes and extracted from them overarching themes pertinent to the nature of the community member's role. In addition, we reviewed the statements by community members during meetings that pertained to the three different views of the community member's role: as the representative of the local community, as the unaffiliated guardian against parochial interests, and as the layperson who can view the research as nonscientists do.

Results

Demographics

There were 29 community members on the 20 IRB panels that we studied. Two community members declined to participate, lowering our total to 27. Three panels had no community members who both attended the observed meetings and consented to participate in our study, so our data on community members derive from 17 of the 20 panels. Several of these panels had multiple community members, including three panels that had three community members and seven panels that had two community members; Table 2 describes demographic information for the 15 community members whom we interviewed and compares them to the 80 non-Chair, nonstaff IRB members who were interviewed (demographic data were not available for participants who were not interviewed). Community members were older than other members ($p < .001$)—perhaps because this role is often filled by retirees—and fewer community members had graduate educations ($p < .001$). All community members were European-Americans.

Community Members as Reviewers

Of the 93 new or revised and resubmitted protocols reviewed by the 17 panels, only two had community members as the primary reviewers (2.7%), whereas community members, who were 17.8% of all members, constituted 18.0% of the secondary or tertiary reviewers. The difference in the distribution of reviewer roles for community versus noncommunity members was statistically significant ($X^2(1) = 9.19$, $p = 0.002$). Many of the community members whom we interviewed explained that they rarely serve as primary reviewers

because they were not expert in the technical issues of medical research that primary reviewers often discuss. The two community members who served as primary reviewers were very experienced with medical research. One was a pediatric nurse with five years of IRB experience, and the other was a retired hospital department administrator who had served as an IRB member for many years before retirement and continued to serve as a "community member" after retiring in spite of his previous connection to the hospital. The following analyses that compare community members as reviewers with noncommunity members as reviewers exclude the two occasions on which the former functioned as primary reviewers because of the small number of such events. In all of the analyses, we excluded IRB chairs and staff members since they have prescribed roles that are markedly different from the roles of other members and thus affect their participation rates and the topics about which they speak.

Community members served as secondary or tertiary reviewers on 11 new protocols. Eight of these protocols involved interventions and three were observational studies. The topics of these protocols varied widely. When acting as secondary/tertiary reviewers, community members spoke significantly less than other reviewers: a mean of 6.9 vs. 12.8 speaking turns/person/protocol (see Table 3). However, when they were not acting as reviewers but simply participating as general members of the committee, the community members had significantly more speaking turns than other members: 2.7 vs. 1.3 speaking turns/person/protocol. The interaction between whether the speaker was a reviewer of the protocol and whether he or she was a community member was significant at the .001 level.

Table 4 presents data about the topics that community members discussed compared to those discussed by other members as secondary or tertiary reviewers. 39.5% of community members' speaking turns included discussions of consent, compared to only 30.3% of the speaking turns of other members when acting as reviewers. However, when included in the mixed-models Poisson regression, this difference was not significant. As reviewers, community members were more likely to speak about issues of confidentiality (25.0% of speaking turns compared to 4.8% for other members, $p < 0.000$). There were no other significant differences between community members when they were secondary/tertiary reviewers and other secondary/tertiary reviewers on the other topics discussed.

Community Members as Nonreviewers

Table 5 compares topics discussed by community members as nonreviewers with topics for other members in the nonreviewer role. 20.8% of the community members did not speak at all during the observed meetings. However, this is nearly identical to the finding that 20.7% of all attendees at the meetings did not speak (Candilis et al., in press). When they spoke, 47.3% of community members' nonreviewer speaking turns included statements about consent, compared to only 20.4% of the speaking turns of other members ($p = .000$). On the other hand, community members spoke less about safety monitoring issues (0.5% vs. 3.1% of speaking turns, $p = 0.012$). Candilis et al. (in press) report that the extent of nonparticipation among IRB members correlates with the size of IRB meetings.

Community Member Interviews

Two themes appeared consistently in the community member interviews. First, although as noted, two community members did serve as primary reviewers, they both had extensive healthcare expertise. However, 11 of the 15 community members explicitly said they felt that reviewing the scientific aspects of protocols was either beyond their comprehension or not their responsibility. For example, one community member said, "I wouldn't feel comfortable being a primary reviewer, as I know I'm not going to be able to really delve into the…to the technical/medical aspect of the protocol." One described his discomfort

when, on one occasion, the primary reviewer had not shown up and he was forced to discuss the medical aspects of the protocol. This is hardly surprising. No source in either the regulations or the literature suggests that community members should focus on the medical and scientific aspects of research protocols.

Instead, community members stated that their responsibility was to take the perspective of potential research participants when reading protocols and consent forms. As one participant stated, "My value to the committee is to try to stay as naïve as I can, you know, when I read this stuff…how would a naïve person read this?" Other community members said: "I read it with a viewpoint that I'm representing the layperson. See if they can understand it," and "I think that's what my role is. I'm standing in for the subject." Specifically, assessing the readability of the consent form was consistently mentioned as an important part of their job, including ensuring that consent forms are understandable to potential participants. One participant stated that the community member's job was to check to see that "it's not too technical…that they can comprehend what they're signing. You know what they're gonna do…so they can be readable by a person without a college education."

Equally important is what they did not say. No community member suggested in their interviews that they saw their role as assuring that the public interest was protected from conflicts of interest. This is similar to their behavior during meetings. At no time during a meeting did any community member discuss conflict of interest of the institution, the committee, or even the researchers. Likewise, in their interviews, the community members did not discuss the community in which they lived or their responsibility to it. The same was true of their behavior in the meetings. They made no reference to the local community or its values.

Discussion

What role then did these unaffiliated community members actually play? One possibility is that they acted just like other members. Our data has shown that this was clearly not true. Both their actions and their self-definitions are clearly different from the affiliated members of the committee. They were less likely to be primary reviewers, reflecting the general perception among medical IRBs that primary reviewers should have technical/medical expertise. Their lack of medical expertise may have led them to be less active as secondary reviewers, and to focus on less technical aspects of the protocol. In contrast, community members were significantly more active in commenting on protocols when others were the designated reviewers.

Given that they were different, in what way were they different? Three models have been suggested for community members. The regulations describe them as "unaffiliated," suggesting protection against the parochial interests of the institution. Neither in the interviews nor in their behavior in meetings did community members appear to see this as their role.

Another model is implied by the concept of "community." Sometimes this term is used to represent ethnic minorities. However, in spite of the fact that the broader population was primarily not European in ancestry at 5 of the 10 sites where we observed IRBs, all of the community members were of European ancestry. Another meaning of "community" refers to the population and mores of the locality. Thus community members might be concerned with how the research fits into the needs and concerns of the locality. However, neither in their interviews nor in their participation in meetings did they discuss any issues concerning the local community.

Instead the community members acted, as Veatch suggested, as laypeople. That is, rather than playing the role of unaffiliated guardians against conflicts of interest alluded to in the regulations, they acted as nonscientific members who focused on a particular subset of issues. Community members saw themselves as having a particular kind of expertise—the *person whose expertise comes from a lack of specialized knowledge*. Because they lacked medical knowledge, they felt empowered to focus on the comprehensibility of the consent form to the lay-person and to a lesser extent on issues related to protection of subjects' confidentiality.

It is a limitation that in this first study with observational data on community members' actions during IRB meetings, we collected data on only 20 IRB panels, only 17 of which had participating, consenting community members. Another limitation is that we were not able to count the words per speaking turn or examine the content of members who did not consent to have their comments transcribed. Finally, our findings may not be representative of smaller, less active IRBs or nonbiomedical IRBs.

Despite these limitations, a pattern seems clear. With few exceptions, IRBs did not use their community members as primary reviewers; and even in the secondary reviewer role, they seemed to have a more limited focus than other members of the committees. They did not act as community representatives in any meaningful sense or as a bulwark against the institutions' parochial interests, but rather assumed the role of naïve nonscientists who looked at the research as they thought other nonscientists would when considering whether to participate in research studies.

This raises a problem. If one's expertise depends on one's lack of knowledge about the nature and details of research, does participation on an IRB over time undermine the outsider's expertise? How long can one maintain one's naïveté when routinely listening to discussions about, and critiques of, research protocols? Perhaps the longer community members participate on an IRB, the more their activities begin to look like those of affiliated scientific members. If so, it raises the possibility that community membership on an IRB should be time-limited to preserve that perspective. Addressing these questions, however, will require further research.

Best Practices

The data presented here should raise questions about the nature of the participation of community members. IRBs need to assure that community perspectives are included in each review of a protocol, and hence might consider formalizing a special role for community members. Instead of having community members serve as undifferentiated secondary reviewers, which deviates from their own conception of their function on the IRB, the specialness of their role could be emphasized, namely to address human subjects issues from the perspective of research participants. Community members, in this model, would focus on reviewing the appropriateness of the proposed consent process, the comprehensibility of the consent form, and the adequacy of protections for confidentiality. Such a "job description" would play to the strengths of community members and help IRBs focus on important issues that might otherwise attract less attention than they deserve. Training from educational organizations such as PRIM&R can help reemphasize the importance of community contributions to the discussion of each protocol.

Research Agenda

There remain many unanswered questions about the role of community members on IRBs, including the *range* of roles they play in IRB decision-making and how their roles are related to their background and expertise. In our sample there were only two community members

who served as primary reviewers. We suggested that this unusual role might reflect their background in healthcare, but two individuals can only be the basis for a hypothesis. Many more community members served as secondary reviewers. We found that overall they were less active in this role than other members, but it might be that some individuals with specific types of experience play this role better than others. Would a redesigned role for community members such as we suggested above add to their utility for IRBs? Likewise, does a shorter or longer tenure on the committee strengthen the role? Only an experimental design can ultimately answer these questions.

We also found only European-American community members. Is this a common pattern or simply something that resulted from our relatively small sample? A broad survey would answer this question better than our methods can. Further exploration of the ways in which community members function on IRBs might help in assessing the value of the existing requirement for community members on IRBs and further clarify its utility.

Educational Implications

The data on IRB community members, from prior surveys as well as the content analysis of meetings that we have described here, is an appropriate foundation both for the recruitment of future IRB members and for the planning of training for future community members. The discussions in the 1980s on the nature and role of the “ideal” lay member can be augmented by the new data on the contributions of community members. This improved understanding of the role of community members will allow us to improve the focus of their training and increase the effectiveness of community members in their role.

Acknowledgments

The authors gratefully acknowledge the help and assistance of the anonymous IRB staff and members who encouraged and supported our work as well as the PIs at each site. We also appreciate the following individuals who substantially contributed to the study: for data collection Jill Rosenbaum, Christopher Jackson, and Teresa Roach; for data coding John Grillo and Linda Doucette.

This study was funded by a grant from the National Cancer Institute, 5 R01 CA107295.

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Biographies

Charles W. Lidz, PhD, is Research Professor of Psychiatry at the University of Massachusetts Medical School. He was the PI on this study of IRB practices. This study continues Dr. Lidz's extensive research in issues related to research ethics.

Lorna J. Simon, MA, was the data analyst on this study of IRB practices, focusing on the cleaning of the data files for this paper and performing the statistical analysis. Ms. Simon contributed both her data analytic and writing expertise to this paper.

Antonia V. Seligowski, BA, was part of the team that collected the data on this study of IRB practices. Along with interviewing participants, she also participated in the coding of the interviews. Ms. Seligowski was also a major contributor in the writing of this paper.

Suzanne Myers, BA, was the Project Director on this study of IRB practices. Ms. Myers played major roles in the data collection and coding and was also a major contributor in the writing of this paper.

William Gardner, PhD, was a co-investigator and the supervising statistician on the study of IRB practices. Dr. Gardner supervised Ms. Simon's analysis of the quantitative data. Dr. Gardner also wrote and rewrote substantial sections of this paper.

Philip J. Candilis, MD, was a co-investigator on this study on IRB practices. He played a major role in supporting data collection and oversaw coding. Dr. Candilis's participation in this study furthers his interest in research ethics. Dr. Candilis was also a major contributor in the writing of this paper.

Robert Arnold, MD, was a co-investigator on this study of IRB practices. This study continues Dr. Arnold's extensive work on medical ethics. Dr. Arnold also contributed by writing and rewriting several drafts of this paper.

Paul S. Appelbaum, PhD, was a co-investigator on this study of IRB practices. Dr. Appelbaum's contributions to this study build on his continued research of research ethics. Dr. Appelbaum was also a major contributor in the writing of this paper.

TABLE 1

Characteristics of Protocols Reviewed by the IRBs.

Characteristic	n	%
Field of Medicine		
Infectious Diseases	11	12
Oncology	17	18
Neurology	8	9
Circulatory System	12	13
Other	45	48
Total	93	100
Review Status		
New	77	83
Deferred	16	17
Total	93	100
N of Sites		
Single-site	47	51
Multi-site	46	49
Total	93	100
Therapeutic/Nontherapeutic		
Therapeutic	55	59
Nontherapeutic	38	41
Total	93	100
Study Type		
Observational	21	23
Intervention	71	76
Neither	1	1
Total	93	100
Study Design		
Phase I	12	13
Phase II	28	30
Phase III	26	28
Feasibility	2	2
Laboratory	6	7
Survey/Interview	2	2
Other	17	18
Total	93	100

TABLE 2

Participant Demographic Characteristics.*

Variable	Value	Number of community members N (%)	Number of noncommunity members N (%)	Significance (p) χ^2
Gender	Male	9 (60)	50 (63)	n.s.
	Female	6 (40)	30 (38)	
Ethnicity[1]	European Descent	14 (100)	66 (89)	n.s.
	Non-European	0	8 (11)	
Age[2]	Age: 24–40	1 (8)	15 (20)	0.001
	Age: 41–50	0 (0)	24 (32)	
	Age: 51–60	4 (31)	26 (35)	
	Age: > 60	8 (62)	10 (13)	
Education	Bachelor's degree or less	6 (40)	6 (8)	0.003
	PhD/MD/JD/MA	9 (60)	74 (93)	
Years of IRB Experience[2]	≤ 5	8 (57)	42 (55)	n.s.
	> 6	6 (43)	34 (45)	
Total		15 (100)	80 (100)	

*Data represents participants who attended an IRB meeting and were interviewed

[1]Seven missing

[2]Five missing

TABLE 3

Speaking Turns/Person/Protocol.

	Speaking turns/per person/per protocol Mean (CI)	Significance (p)
Community member reviewer	6.9 (5.4–8.6)	.05
Other member reviewer	12.8 (11.8–13.8)	
Community member nonreviewer	2.7 (2.4–3.0)	.03
Other member nonreviewer	1.3 (1.2–1.4)	

TABLE 4

Topics Addressed by Percent of Speaking Turns for Secondary/Tertiary Reviewers: Community Members vs. Other IRB Members.

	Community Members (n= 11)	Other IRB Members (n=15)	Significance (p)
Risks	15.8 (8.8–26.4)	19.4 (16.4–22.7)	n.s.
Risk/Benefit	0.0 (0.0–6.0)	1.3 (0.6–2.5)	n.s.
Consent	39.5 (28.7–51.4)	30.3 (26.8–34.1)	n.s.
Equitable selection of subjects	1.3 (0.1–8.1)	7.8 (5.9–10.2)	n.s.
Vulnerable populations	6.6 (2.4–15.3)	7.8 (5.9–10.2)	n.s.
Safety monitoring	3.9 (1.0–11.9)	2.7 (1.6–4.3)	n.s.
Confidentiality	25.0 (16.1–36.5)	4.8 (3.4–6.9)	0.000

The sample size represents the total number of secondary/tertiary reviewers for each role category (community members and other IRB members) for the 93 protocols studied.

Because of nonnormal distributions and the nested nature of the variables, significance was calculated using mixed-models Poisson regression with participants as a random effect.

TABLE 5

Topics Addressed by Percent of Speaking Turns for Nonreviewers: Community Members vs. Other IRB Members.

	Community Members (n= 11)	Other IRB Members (n=15)	Significance (p)
Risks	20.1 (16.4–24.5)	19.0 (16.6–21.6)	n.s
Risk/Benefit	0.7 (0.2–2.4)	1.3 (0.6–2.5)	n.s.
Consent	47.3 (42.3–52.3)	20.4 (18.0–23.1)	0.000
Equitable selection of subjects	5.5 (3.5–8.3)	4.7 (3.5–6.3)	n.s.
Vulnerable populations	9.0 (6.4–12.3)	7.7 (6.1–9.5)	n.s.
Safety monitoring	0.5 (0.1–2.0)	3.1 (2.1–4.4)	0.012
Confidentiality	1.5 (0.6–3.4)	2.8 (1.9–4.0)	n.s.

The sample size represents the total number of secondary/tertiary reviewers for each role category (community members and other IRB members) for the 93 protocols studied.

Because of non-normal distributions and the nested nature of the variables, significance was calculated using mixed-models Poisson regression with participants as a random effect.