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IRBs and Ethically Challenging Protocols: Views of IRB Chairs about Useful Resources

Nicole Sirotin, MD[Assistant Professor],
Albert Einstein College of Medicine/Montefiore Medical Center, New York, NY

Leslie E. Wolf, JD, MPH[Associate Professor of Law],
Georgia State University College of Law, Atlanta, GA

Lance M. Pollack, PhD[Specialist],
University of California, San Francisco, CA

Joseph A. Catania, PhD[Professor],
Oregon State University, Corvallis, OR

M. Margaret Dolcini, PhD[Associate Professor], and
Oregon State University, Corvallis, OR

Bernard Lo, MD[Professor of Medicine]
University of California, San Francisco, CA

Institutional review boards (IRBs) often review research protocols that raise significant ethical issues. Such issues include informed consent for research with vulnerable populations, including those who may lack decision-making capacity; potential risks of studies that involve medication withdrawal; the use of placebo-controlled trials; and the privacy and confidentiality of sensitive research data.[1] Yet some IRBs may not have experience reviewing protocols that raise these and other ethical challenges. Various types of resources have been proposed to provide specific and practical guidance to help IRBs achieve their goals of protecting research participants. These include education and training programs,[2] increased guidance from the federal Office for Human Research Protections (OHRP),[3] Web site development,[4] and increased access to experts in science and clinical medicine, as well as to the perspectives of research participants.[5] Little is known, however, about what resources IRBs consider useful in providing guidance about how to respond to ethically challenging research.

As part of a larger interview study of IRB chairs who review mental health research, we asked the chairs to rate the helpfulness of specific resources for assisting their IRBs with reviewing research protocols. IRB chairs are an important source of information on this issue because, compared to the average IRB member, they typically have more experience reviewing research protocols. Thus, IRB chairs may function as the “long-term memory” of the IRB and as a consequence, their opinions carry considerable weight on their IRBs.[6]

Study Methods and Survey Sample

The data for this study were collected as part of a national survey of IRB administrators and IRB chairs who review mental health research, although the survey questions for the present study were not specific to mental health research.[7] We sampled Institutional Review Board Organizations (IORGs—a designation used by OHRP to identify related IRBs) from a data set provided by OHRP. The IORG file was stratified into two tiers. Tier one consisted of 120 IORGs representing the top 100 institutions in terms of fiscal year 2002 funding from the National Institutes of Health (NIH). Tier two included the 1,938 remaining IORGs (10

pretest IORGs and the IORGs encompassing the two IRBs that reviewed and approved the protocol for this study were excluded). IORG administrators were asked to enumerate the IRBs within their organization and the membership of each IRB, as well as to answer questions about workload.

Eligible chairs were identified from the information collected during the administrators' interview. Because of the focus of the main component of the study, only chairs of IRBs that reviewed mental health-related research were eligible for the present chairs' study. Only one chair per institution was interviewed, and we oversampled for tier one, nonwhite, and female chairs to ensure sufficient numbers in these groups for analytic purposes. The vast majority of institutions were represented by a single IORG with only one IRB, and that IRB was eligible because it reviewed mental health-related applications. However, if an institution had multiple IORGs and/or IRBs that yielded more than one eligible chair and the oversampling plan did not designate which chair should be interviewed, then one of the eligible chairs was randomly selected to represent that institution.

Procedures

Trained interviewers contacted chairs by telephone, e-mail, or letter requesting participation. Chairs who verbally consented to participate were rescreened to confirm eligibility. Several were found to be ineligible because, contrary to the information provided by the IORG administrator, they did not review mental health-related applications. In all such cases, more than one IRB at that institution reviewed mental health-related applications. Thus, ineligible chairs were replaced with an eligible chair from the same institution. Eligible chairs were offered $25 as an incentive to participate, which they could elect to donate to the charity of their choice. All chair interviews, except for a brief demographic questionnaire (which could be completed by telephone or by a self-administered written questionnaire), were conducted over the telephone between October 2005 and June 2006. The interviews were recorded and transcribed verbatim. Transcripts were reviewed for accuracy and thoroughness of the transcription, and all identifying information was removed from the transcript and replaced by a unique ID number. Anonymized transcripts were uploaded into ATLAS.ti for coding.

Measures and Statistical Methods

Data collection in the survey of IRB chairs included a brief demographic survey that asked questions about IRB size, composition, and workload during the past year. This was followed by a semistructured interview in which chairs were first asked to respond to two of three possible research scenarios that portrayed ethical issues involving mental health-related research. The three research scenarios involved: 1) withdrawal of medication for psychiatric illness in children; 2) DNA analysis of stored samples; and 3) a survey of mental health problems in homeless persons. Using primarily open-ended questions, chairs were asked to identify any ethical concerns they had regarding each scenario and to make suggestions on how these concerns should be addressed. They were then asked to indicate whether they found specific resources or suggestions helpful when faced with a protocol that raises serious issues regarding protections for research participants. Specifically, chairs were asked: "When faced with a protocol that raises serious issues regarding human participants protection, which of the following would you find helpful?"

- Talking to other IRB members before the formal meeting.
- Talking to scientific colleagues who are familiar with this kind of research.
- Talking to colleagues at other IRBs.
- Talking to experts in research ethics or bioethics.
- Looking up pertinent articles or books.

- Using Internet resources, such as the IRB Forum listserv, for discussions of similar protocols.

They were also asked whether the following resources would "be helpful to your IRB in reviewing a protocol that raises ethical concerns":

- More specific guidelines from the federal Office for Human Research Protections on interpreting "minimal risk."
- Obtaining guidance from the federal Office for Human Research Protections on this particular protocol, without triggering an investigation.
- More IRB access to experts in the relevant scientific disciplines.
- More IRB access to individuals who can articulate the perspective of participants in such a study.
- More IRB access to experts in research ethics.

Our study suggests that IRB chairs, arguably the most experienced and influential members of their IRBs, see a need for access to different perspectives—from scientific, research ethics, and participant communities—to help them address the ethical challenges that they face, rather than expanded guidance from OHRP.

For each item, the respondent could rate the predetermined response set as very helpful, somewhat helpful, somewhat unhelpful, or very unhelpful. Although not asked to do so, when chairs spontaneously commented in their responses, the comments were recorded and transcribed verbatim. The first two authors analyzed these comments for content and selected comments to represent common themes, as well as the range of variation in comments, both negative and positive, regarding each resource.

A two-tailed Fisher's Exact Test was used to determine whether the proportion of chairs who responded "very helpful" to each of the 11 items varied by individual, IRB, or institutional characteristics. Individual characteristics included age, gender, race, degree, job title, years on the IRB, years as IRB chair, experience with human subjects research, experience conducting mental health-related research, and attendance at a conference on human subjects protection in the past three years. IRB characteristics included number of new protocols reviewed annually, number of new protocols per member per year, number of mental health-related applications reviewed, number of mental health professionals on the committee, number of nonstaff IRB committee members, number of nonscientific members, and number of noninstitutional members. The sole institutional characteristic was level of NIH funding in FY2002 (tier one vs. tier two).

Respondent and Institutional Characteristics

The screening of 244 IORGs generated information on 400 IRBs, of which 255 reviewed mental health research applications. We selected 131 of those 255 IRBs for the chair survey, which was limited to one chair per institution, included all tier one institutions, and gave preference to nonwhite and female IRB chairs. Thirteen chairs (9.9%) were nonwhite. Most chairs represented the sole IRB at their institution (85%). The final sample of interviewed IRB chairs (N = 85) is estimated to represent 5.5% of all IORGs that held a Federalwide Assurance with OHRP in 2005–2006 and reviewed mental health-related protocols. The chair sample comprised 32 chairs from IORGs at the 100 institutions receiving the most NIH funding (participation rate 60%), and 53 chairs from all other institutions (participation rate 68%). The overall participation rate was 65%. Table 1 presents the characteristics of the 85 IRB chairs interviewed; Table 2 shows the characteristics of their IRBs and institutions. The chairs were mostly Caucasians with doctoral degrees who were tenured faculty at

academic institutions. Respondents generally had considerable experience as IRB members and IRB chairs, and most had personal experience conducting human subjects research.

Perceived Helpfulness of Resources

Table 3 presents the chairs' ratings of the helpfulness of various resources and suggestions for dealing with human participant protection issues raised in research protocols. Sixty percent or more of the chairs rated four of the resources as very helpful: scientific colleagues; individuals articulating participant perspectives; research ethics experts; and Internet resources. Respondents' open-ended comments revealed their experiences with, preferences for, and reservations about the resources and suggestions. Most chairs (69/85, 81%) offered at least one unsolicited comment beyond simply rating the suggestion helpful or unhelpful. The bottom quartile, median, and upper quartile were one, two, and five topics commented upon, respectively, and the range was 0–11. The mean was 3.26. The fewest chairs (17) commented on the helpfulness of having access to scientific experts, and the most (36) commented on the helpfulness of seeking guidance from OHRP (mean = 26 chairs commenting on the topic). Respondents did not answer all questions, resulting in sample size variation among questions.

Scientific Colleagues

Chairs overwhelmingly found "talking to scientific colleagues who are familiar with this kind of research" very helpful (65/85, 76%), and no chair rated it unhelpful. They reported that such discussions were common and may occur informally on an individual basis or formally before the IRB. In the latter case, the IRB may add an ad hoc reviewer or invite an expert to attend a meeting to provide information and answer questions about one or more protocols. However, chairs raised concerns about confidentiality when talking to colleagues not on the IRB. As one chair cautioned, "You have to be careful of privacy issues, there are a number of areas here where this gets sticky." Another chair expressed concern about informal consultations, with members "just wandering around the halls talking to someone who [they] think is an expert or something." Not surprisingly, the majority of chairs (52/83, 63%) also felt more IRB access to experts in the relevant scientific disciplines would be very helpful. A number of chairs commented that they routinely seek out the scientific expertise they need, implying they have access to it. However, chairs also pointed out some problems. In particular, one respondent noted the challenges related to international studies: "We do have difficulty sometimes in finding expertise for different cultural areas. … So we have to know somebody who knows Mozambican culture." Moreover, even an experienced chair at a high-volume institution expressed concern about access to experts from pertinent disciplines: "We still continue to struggle getting certain disciplines onto our panel. It's a large time commitment."

Participant Perspectives

Sixty-five percent (53/81) of chairs indicated that it would be very helpful to have more IRB access to individuals who can articulate the perspective of the participants in a study. Several of these comments emphasized the value of this particular perspective. One chair reported that "almost a third of our members are people like that. They contribute immensely to the deliberation of the committee." A handful of respondents expressed concern that such access was lacking on their current committee. Said one chair: "I think that we don't have as many community representatives as we could and continually struggle with finding committee members."

Research Ethics Experts

Sixty percent (50/83) of IRB chairs stated that talking to experts in research ethics or bioethics would be very helpful, but only 42% (34/82) felt more IRB access to experts in research ethics would be very helpful. Most chairs said that they had good access to this type of expertise—perhaps because, as one chair noted, “We all think we are experts.” However, one chair from an IRB that reviewed a low volume of protocols indicated a lack of access to ethical expertise. In addition, a few chairs expressed reservations about the usefulness of such experts. One chair commented negatively on ethics experts who lacked real-world experience, calling them “philosophical parasites.” Another chair laughed and characterized the potential discussion as “Confusing!” and another responded, “Almost never helpful!” Some feared that such members would hinder discussion: “I am concerned. You’ve got 15 people in there to get their opinion and if two people say, ‘Oh, I think this is terrible or something.’ And then you’re sort of stuck.” Another acknowledged, “I think that access to someone who is well versed in research ethics is helpful. Having too many of them all the time, I think it’s a problem.” One chair raised concerns about the effect on the researcher: “I think people are sensitive when you challenge their ethics or you feel like they need to learn something or be taught, rather than keeping an open mind to it.”

Internet Resources

When asked about using Internet resources such as the IRB Forum listserv for discussions of similar protocols, 46% of participants (38/82) felt it would be very helpful. However, awareness and use varied considerably. Eight of the chairs who thought such a resource would be very helpful had never used the IRB Forum, and four of them did not even know such a resource existed. On the other hand, seven of the chairs who rated Internet resources as very helpful commented that they had used the IRB Forum. Reviews of the usefulness of the IRB Forum as a resource were mixed. One chair whose IRB committee frequently uses this resource felt it was valuable for general information: “We don’t use it for specific protocols but we pass around the IRB forum chitchat on issues that we’ve been grappling with or to raise questions.” Another participant echoed, “if it’s sufficiently generic and if you’re not asking other people for input, if you’re instead looking through old discussions, it would be very helpful.” On the other hand, one chair had misgivings about the quality of discussion: “I think, because the level of understanding on that forum is pretty low, it’s hard to find useful information. I think there’s a bit of misinformation.” Finally, some chairs expressed concern about time, efficiency, and practicality. Typical comments included: “It probably just clogs up my email,” and “it can literally just drown you … I already get a couple hundred emails a day; I don’t always have time for a couple hundred more emails.”

Articles or Books

When asked about looking up pertinent articles or books, 39% (32/83) said doing so was very helpful. While some IRB chairs felt the practice was “mandatory” and affirmed that an article is sent out with every meeting, others raised concerns about practicality and feasibility. For example, one chair responded, “Yeah, if you had the time.” Another chair noted, “We’re extremely busy so very rarely do we have time to sit and do literature reviews.” One respondent believed it would be better to talk to an expert directly: “We would rather have somebody who understands that literature rather than try to interpret it ourselves.”

IRB Members

Just over a third (28/82) of respondents stated that talking to other IRB members before the formal meeting would be very helpful. Several who said they actually do so expressed reservations about this practice. Some felt that talking to other IRB members before the

meeting violated proper procedure. According to one chair, “there’s nothing that should be discussed outside of an IRB meeting which shouldn’t be discussed … in the IRB meeting, that’s [privy] for everybody so I’m not even sure it really should be done.” Another IRB chair was concerned that discussions outside of the group might prejudice the individual reviewers: “I like to hear the information all at once and if I’m talking to someone before then, I think I’m entering my own biases into it one way or the other. So I’d like to hear the larger group participation in the group. I think it’s a group process that’s really important.” In a similar vein, one chair said, “I want every IRB member to be an equal, I want every voice heard.” In contrast, several chairs noted that such discussions could help clarify issues before a meeting; approximately one-third (27/80) of respondents felt talking to colleagues at other IRBs would be very helpful. Chairs commenting on this issue mostly expressed reluctance to talk to other IRBs. As one chair explained, “Decisions about the IRB have to do with your institution and the conditions and situations that are in your community.”

OHRP Guidelines

Only 33% (27/82) of chairs felt that more specific guidelines from OHRP on interpreting “minimal risk” would be very helpful. Moreover, almost one-third (26/82) felt such guidance would be unhelpful. In support of the current guidelines, one chair stated: “I think they’ve got pretty far on it. I don’t know how much further they can go.” In contrast, others felt the current guidelines were “undecipherable” and what was needed was a “user-friendly definition.” Most of the chairs commenting on this issue expressed concerns that additional guidance would create more problems. For example, one respondent was concerned with preserving the IRB’s ability to evaluate protocols on a case-by-case basis: “If you put too much guidance and too many criteria and too many guidelines, you’re basically doing a boilerplate and you’ve diminished the custom of looking at each study, with its unique circumstances.” One described further guidance from OHRP as a “double-edged sword. On the one hand you’d like to have very exclusive guidance, on the other hand you might not agree with it.”

Protocol-Specific OHRP Guidance

Thirty percent (24/80) of chairs felt that obtaining guidance from OHRP on a particular protocol, without triggering an investigation, would be very helpful, whereas approximately one-quarter (19/80) of chairs considered it unhelpful. Some expressed concern that questions to OHRP might lead to an investigation: “That’s a big caveat there!” “It opens up a can of worms.” Others found information from OHRP to be unhelpful: “Often you get back pretty standard stuff.” Another stated, “They have to be so neutral and unbiased that it’s just somewhat unhelpful,” and another considered it a “waste of the time.” The feasibility of consultation with OHRP was also questioned by one of the chairs: “With the number of protocols the IRBs have to review and the speed with which we have to get stuff through, if we had to go to OHRP to get an advisory opinion, we may as well deny straight off the [bat] because it’s just going to take too long and it’s just not going to be feasible.”

IRB Characteristics and Helpful Resources

Of the characteristics we tested, chairs of IRBs with lower protocol volume were more likely to respond that increased Internet resources and increased access to ethics experts were “very helpful.” However, chairs at institutions receiving higher levels of NIH funding, with experience in human research, or who attended a human subjects protection conference in the past three years were less likely to rate those items as “very helpful” (Tables 4 and 5).

Discussion

The majority of chairs we surveyed said that when reviewing ethically challenging research protocols, talking to experts in research ethics would be helpful, and many expressed comfort with their access to such experts within their IRB or institution. However, some respondents expressed concerns about the quality of advice from experts in research ethics. In particular, chairs noted the need for advice that is grounded in practice. The burgeoning research ethics consultation movement in research institutions may help meet this need for high-quality advice. Yet having both IRBs and investigators as clients may create conflicts of interests.[8] Pooling resources, as some institutions that are recipients of Clinical and Translational Science Awards (CTSAs) are doing, might be one way to address some of these concerns.[9] The challenge is to bring those services and expertise beyond the relatively small number of CTSA recipients.

In addition, many chairs desired further input from laypersons who can articulate the perspective of the study participants. Previous studies have shown that nonscientific members of IRBs often feel isolated and intimidated by the scientific members of IRB committees.[10] Lay members may feel more integrated into the IRB review process if their number is increased and if they are provided more training both in-house and through conferences. However, given the challenges of recruiting lay members, IRBs should also consider other ways to get this important perspective represented in the IRB review process. For example, as has been suggested in the context of research ethics consultation, professionals who work extensively with prospective research populations could help articulate those perspectives and should be encouraged to formally explore those perspectives, perhaps through focus groups and interviews.[11] Similarly, IRBs might also work with research subject advocates, who work closely with research participants and seek to represent their perspectives.[12]

Our respondents also expressed reservations about several suggested resources for helping with the ethics review of research protocols. Some chairs emphasized the need for confidentiality and preserving the standard review process when consulting with scientific or ethics experts. The majority of chairs did not consider certain resources very helpful, such as more guidance from OHRP. Although the National Bioethics Advisory Commission (NBAC) and various Institute of Medicine (IOM) reports have advocated more guidance from OHRP to clarify ambiguities in the federal research regulations,[13] some respondents were concerned that such guidance would be unclear or undermine IRB discretion. Furthermore, some respondents suggested that asking advice from OHRP on a specific protocol might trigger an investigation or slow down the review process. These results are consistent with concerns that OHRP focuses on regulatory “minutiae” and that it might “impose draconian penalties for minor infractions.”[14]

Several characteristics were associated with chairs finding certain resources for assistance helpful. Chairs with less personal experience with human subjects research, whose IRBs reviewed fewer protocols than other IRBs in our sample, and whose institutions fell outside the top 100 in NIH funding were more likely than the other chairs in the study to endorse access to Internet resources and access to experts in research ethics as being very helpful. This implies that less-experienced IRB chairs might benefit from assistance targeted to them, such as an IRB forum Web site for inexperienced chairs that is moderated by a more experienced chair or perhaps an educational course offered by Public Responsibility in Medicine and Research (PRIM&R) or another organization targeted to less experienced chairs and those who review a low volume of protocols.[15] New IRB chairs also might receive mentoring from more experienced local chairs, similar to the national mentorship program that PRIM&R offers. In addition to targeted training, real-time assistance might be

useful, such as a funded national hotline for questions in research ethics, similar to hotlines for difficult clinical issues such as management of needle sticks or management of drug-resistant tuberculosis.[16] Chairs who attended conferences on human subjects protections, such as the PRIM&R "IRB 101" and annual Advancing Ethical Research Conferences,[17] were less likely to consider more access to research ethics experts very helpful; perhaps the substantive information and networking opportunities provided by these conferences obviate that need. If so, institutions may want to encourage attendance by paying for the costs and providing protected time for attending such conferences.

There has been debate about whether IRBs should include scientific review as part of their charge.[18] Some have suggested that IRBs may not have sufficient relevant expertise to conduct scientific review. However, IRBs are charged with protecting the health and well-being of participants, and they may not be able to fulfill their regulatory and ethical obligations to participants without some attention to evaluating scientific merit. According to Greg Koski, the former director of OHRP, "The notion that scientific and ethics issues can be separated into distinct domains is untenable."[19] Our findings support the view that some scientific review is necessary, as approximately three-quarters of the chairs indicated that talking to scientific colleagues would be very helpful, and almost two-thirds endorse increased access to relevant scientific experts. Our data also suggest that chairs feel they generally have good access to scientific experts, although there may be problems for some. In those cases, relatively simple solutions exist to provide the relevant scientific expertise. For example, investigators of funded research studies could submit the scientific review already performed by the granting agency with the application to the IRB; seeing the review could provide reassurance that the scientific issues have been addressed.[20] In institutions that do not already require prior departmental scientific review for non-funded projects, departments within the institution could identify and provide experts to assist with IRB review on an ad hoc basis.

Our project has several limitations that must be kept in mind. We did not determine how IRB chairs actually obtain assistance with difficult cases; thus, there may be discrepancies between what chairs say they would do and what they actually do. We also did not define "serious issues regarding human participants protection" or "ethical concerns" when asking about what resources or guidance chairs might find helpful. Chairs may have interpreted the phrases in different ways when responding to our questions. In addition, the qualitative comments were unsolicited and therefore may not represent views of the entire sample of respondents. That most chairs made at least one comment suggests that chairs volunteered information when they felt the need to do so. One strength of this study is that it examined a large, national sample that was both stratified and random. This insured that large, well-funded research institutions, as well as smaller institutions, were included. Another strength is the mix of both experienced and inexperienced IRB chairs. And finally, we obtained both quantitative and qualitative data from the participants, with the latter providing a rich variety of quotes that explained some of the former.

In summary, our study suggests that IRB chairs, arguably the most experienced and influential members of their IRBs, see a need for access to different perspectives— from scientific, research ethics, and participant communities—to help them address the ethical challenges that they face, rather than expanded guidance from OHRP. Chairs with less experience in human subjects research feel they would benefit from Internet resources and increased access to ethics experts. Additional empirical work may suggest how IRBs might improve their access to these kinds of resources and, ultimately, should evaluate how that access affects IRB efforts to protect research participants.

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Table 1

Demographic Characteristics of Individual Respondents

Respondent Characteristics	No. (%)
Age	
<50	25 (29%)
>50	60 (71%)
Gender	
Male	44 (52%)
Female	41 (48%)
Race	
White	80 (94%)
Black	1 (1%)
Other	4 (5%)
Degree[1]	
MD+	25 (29%)
PhD+	53 (60%)
Other	10 (11%)
Position	
Nonacademic	15 (18%)
Academic	70 (82%)
Junior Faculty Asst. Professor	5 (6%)
Senior Faculty Assoc. Professor	17 (20%)
Full Professor	28 (33%)
Other	20 (23%)
Number of years on IRB	
<10	48 (57%)
>10	20 (42%)
Don’t know	1 (1%)
Number of years as IRB chair	
<4	45 (53%)
>4	39 (46%)
Don’t know	1 (1%)
Conducted research with human participants	
Yes	73 (85%)
No	13 (15%)
Conducted mental health research	
Yes	28 (33%)
No	57 (67%)
Attended a conference on human protection in past three years	
Yes	61 (72%)
No	24 (28%)

[1] Three chairs fell into both MD+ and PhD+ categories, resulting in an n of 88 for degree.

Table 2

Characteristics of IRBs and Institutions

IRB and Institutional Characteristics	No. (%)
Number of new protocols reviewed per year	
<50	29 (34%)
>50	53 (62%)
Don't know	3 (4%)
Number of new protocols reviewed per member year	
<5	27 (32%)
>5	53 (62%)
Don't know	5 (6%)
Number of mental health-related applications	
0–5	26 (31%)
6–25	29 (34%)
>25	27 (32%)
Don't know	3 (3%)
Number of mental health professionals on IRB	
0–1	30 (35%)
2–3	33 (39%)
>3	21 (25%)
Don't know	1 (1%)
Number of nonstaff IRB members	
2–9	26 (31%)
10–13	28 (33%)
>13	29 (34%)
Don't know	2 (2%)
Number of nonscientific IRB members	
0–3	57 (67%)
>3	27 (32%)
Don't know	1 (1%)
Number of noninstitutional IRB members	
0–2	49 (58%)
>2	35 (41%)
Don't know	1 (1 %)
Institution in top 100	
NIH-funded (tier one)	32 (38%)
Other (tier two)	53 (62%)

Table 3

Respondents' Ratings Regarding Helpfulness of Resources

When faced with a protocol that raises serious issues regarding human participants protections, which of the following would you find helpful?	N Respondents (Comments)	Very helpful	Somewhat helpful	Somewhat unhelpful	Very unhelpful
Talking to scientific colleagues who are familiar with this kind of research	85 (19)	65 (76.5%)	20 (23.5%)		
Talking to experts in research ethics or bioethics	83 (31)	50 (60.2%)	28 (33.7%)	2 (2.4%)	3 (3.6%)
Using Internet resources, such as the IRB Forum listserv, for discussions of similar protocols	82 (31)	38 (46.3%)	34 (41.5%)	10 (12.2%)	
Looking up pertinent articles or books	83 (26)	32 (38.6%)	42 (50.6%)	6 (7.2%)	3 (3.6%)
Talking to other IRB members before the formal meeting	82 (20)	28 (34.1%)	34 (41.5%)	19 (23.2%)	1 (1.2%)
Talking to colleagues at other IRBs	80 (31)	27 (33.8%)	43 (53.8%)	10 (12.5%)	
Would the following be helpful to your IRB in reviewing a protocol that raises ethical concerns?					
More IRB access to individuals who can articulate the perspective of participants in such a study	81 (19)	53 (65.4%)	26 (32.1%)	2 (2.5%)	
More IRB access to experts in the relevant scientific disciplines	83 (17)	52 (62.7%)	24 (28.9%)	7 (8.4%)	
More IRB access to experts in research ethics	82 (21)	34 (41.5%)	38 (46.3%)	7 (8.5%)	3 (3.7%)
More specific guidelines from the federal Office for Human Research Protections on interpreting "minimal risk"	82 (32)	27 (32.9%)	29 (35.4%)	20 (24.4%)	6 (7.3%)
Obtaining guidance from the federal Office for Human Research Protections on this particular protocol, without triggering an investigation	80 (36)	24 (30.0%)	37 (46.3%)	12 (15.0%)	7 (8.8%)

Table 4

Factors Associated with IRB Chairs' Rating of Internet Resources

Characteristic	Category	N	% Very Helpful	p value
NIH funding in FY2002				p = 0.041
	Top 100	32	31.3	
	Other	50	56.0	
Ever done research with human participants				p = 0.010
	Yes	70	40.0	
	No	12	83.3	
Number of new protocols reviewed per year				p = 0.060
	<50	28	60.7	
	>50	51	37.3	
Number of new protocols reviewed per member per year				p = 0.091
	<5	26	61.5	
	>5	51	39.2	

Table 5

IRB Chairs' Ratings of Experts in Research Ethics as Resources

Characteristic	Category	N	% Very Helpful	p value
Attended a conference on human protection in past three years				p = 0.016
	Yes	58	32.8	
	No	24	62.5	
Number of new protocols reviewed per year				p = 0.018
	<50	29	58.6	
	>50	50	30.0	
Number of new protocols reviewed per member per year				p = 0.029
	<5	27	59.3	
	>5	50	32.0	