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IRB oversight of Patient-Centered Outcomes Research: A National Survey of IRB Chairpersons

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Abstract

Patient-centered outcomes research (PCOR) is becoming increasingly common. However, there is little evidence regarding what novel ethical challenges, if any, are posed by PCOR with relevance to IRB oversight and human subjects protections. This article reports the results of a national survey of all IRB chairpersons from research-intensive institutions in the US. Findings address the responsibilities of IRBs and the challenges associated with PCOR review and oversight. IRB chairpersons varied in their judgment of PCOR's overall value to the scientific enterprise and to research at their institution. Furthermore, 27% of respondents considered patients serving in non-

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traditional roles to be research subjects even when they are not enrolled in research. There was also variation in the training and safeguards their IRBs require for patient partners. Our results suggest that guidance should be developed around ethical and regulatory issues associated with PCOR oversight.

Keywords

empirical studies of research ethics; ethics and public policy; human subjects ethics; human subjects regulation and oversight; patient-centered outcomes research

INTRODUCTION

At the turn of the century, the Institute of Medicine established patient-centeredness as one of six core aims of the U.S. health care system.(Institute of Medicine, 2001) Subsequently, the creation of the Patient-Centered Outcomes Research Institute (PCORI) by the Patient Protection and Affordable Care Act of 2010 signaled a foundational shift in how some researchers conduct their work by attempting to promote patient-focused clinical research as a bridge to patient-centered healthcare.(Frank, Basch, & Selby, 2014) Although the definition of Patient-Centered Outcomes Research (PCOR) remains somewhat amorphous, the working definition offered by PCORI is that PCOR “helps people and their caregivers communicate and make informed healthcare decisions” by generating the sort of rigorous data that can help answer questions about what a patient should expect to happen, the potential benefits and harms of various options in comparison to one another, and how to maximize the outcomes that people “notice and care about.”(PCORI, 2018b) The essence of PCORI’s definition “rests on the axiom that patients have unique perspectives that can change and improve the pursuit of clinical questions,” and that researchers and clinicians cannot alone provide the patient perspective due to differences in training and orientation. (Frank et al., 2014)

In order to receive funding from PCORI, investigators must consider including significant patient involvement in all phases of the proposed research—from the identification of research questions, through study design, recruitment, implementation, interpretation of findings, and dissemination of results.(PCORI, 2016) In this regard, PCOR resembles Community-Based Participatory Research (CBPR), which also seeks to include end users in the production of evidence.(PCORI, 2018a) CBPR relies on community knowledge and social action to improve health and address health disparities, a goal that is beyond that of PCOR. However, given its traditionally collaborative approach to research that involves community partners to identify research topics of highest interest, as well as community engagement through data collection and ultimate implementation, CBPR offers important lessons for how best to engage patients in PCOR and the sorts of challenges that may arise. (Sofolahan-Oladeinde, Mullins, & Baquet, 2015) To the extent that Institutional Review Boards (IRBs) struggle with review of CBPR, however, similar issues may arise for PCOR.

PCOR, like other human subjects research, must satisfy a set of regulatory requirements(Department of Homeland Security & Department of Agriculture, et al, 2017) and adhere to well established ethical principles.(Emanuel, Wendler, & Grady, 2000;

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) Early evidence suggests that regulatory and ethical oversight of PCOR might be challenging for IRBs.(L. E. Ellis & Kass, 2017a) For example, in a survey of PCORI-funded principal investigators, respondents identified patient engagement as the second most important potential ethical issue.(Ali, Califf, & Sugarman, 2016) The authors surmised that novel approaches to data capture, recruitment, and privacy, and “overly restrictive interpretations of regulatory language” may have contributed to these challenges.(Ali et al., 2016) In a qualitative study of PCOR stakeholders, our team found that engagement of patients in non-traditional roles and other PCOR characteristics have made PCOR studies relatively more challenging than traditional clinical research studies to oversee.(Largent et al., 2018)

Despite the increasing emphasis on PCOR and patient involvement in research, little is known about the ethical and regulatory oversight challenges faced by IRBs that can make reviewing PCOR protocols difficult to perform in a timely manner. Such knowledge is important, as these difficulties could erect barriers to PCORI’s major initiatives to generate data needed to improve patient care. Moreover, identifying such issues is a first step to targeted interventions to overcome them. As part of a larger PCORI-funded project, the Patient-Centered Outcomes Research Oversight Study (PCOROS), we conducted the first national survey of IRB chairpersons to examine ethical and regulatory oversight issues and concerns associated with PCOR.

METHODS

Sample, Survey Development, Testing, and Administration

We obtained lists of IRB chairpersons from the US Office for Human Research Protections (OHRP) for all US medical schools (n=138), schools of public health (n=61), and hospitals (n=68) that had obtained funding from the National Institutes of Health (NIH)(NIH, 2016) in 2015. We chose these institutions because their IRBs are most likely to oversee PCOR now or in the future. All IRB chairpersons from these institutions who were registered with OHRP, for whom we could find contact information, and who were chairs of IRBs reviewing healthcare related research protocols were included in the study.

Development of the survey domains was informed by previous surveys(Campbell et al., 2006; Weissman, Koski, Vogeli, Thiessen, & Campbell, 2008) and qualitative research performed as part of PCOROS, which included input from IRB members and chairs, investigators, ethicists, regulators, and others.(Largent et al., 2018) The major domains included PCOR experience, processes and procedures, challenges in review and oversight, handling of patients in non-traditional research roles, and the need for guidance. Based on our qualitative work, we defined PCOR as “the evaluation of questions and outcomes that are meaningful and important to patients and caregivers, and that engages patients beyond their traditional role as research subjects.” Note that this definition expands on that offered by PCORI by focusing on the specific roles of patients as research partners. We then elicited respondents’ opinions about the value of PCOR and how it differs from non-PCOR. We did not specifically link PCOR to CBPR, or ask about CBPR separately.

Survey items were cognitively tested with 8 IRB chairpersons (including 3 ex-chairs) to identify questions that were difficult to understand or answer and to ensure uniformity of comprehension; cognitive testing was followed by a formal mailed pretest to 10 chairpersons. The final survey instrument was 8 pages long, contained 35 items, and took approximately 15 minutes to complete. (Appendix)

The Nielsen Company administered the survey by mail between November 2016 and April 2017. Subjects were sent the questionnaire, a postage-paid return envelope, \$20 cash incentive, and an introductory letter containing a web link for those who wished to respond on-line. To enhance the response rate, three rounds of mail, email, and telephone calls were made. Respondents were promised confidentiality of their responses. The study was determined to be exempt by the Institutional Review Board at Partners Healthcare.

Respondent characteristics, value of PCOR, and PCOR review experience

Respondents were asked to report the number of years they have served as chair, their age, sex, race-ethnicity, and academic rank. Respondents also reported on the volume of all protocols reviewed by all IRBs at their institution, the volume of new PCOR protocols in their most recent year as chair, and their own experience reviewing PCOR. Respondents who reported either the occurrence of new PCOR protocols, or who personally reported ‘some’, ‘a little’, or ‘a lot’ of PCOR experience, were categorized as having “some” PCOR experience; otherwise they were categorized as having “none”. Respondents skipped or otherwise opted out of selected questions, e.g., about their IRB practices, if they had no experience reviewing PCOR proposals.

Challenges to IRB review and oversight due to patients in non-traditional roles

A central goal of the study was to identify and quantify challenges encountered by IRBs reviewing PCOR protocols. The key feature of PCOR that sets it apart from other biomedical research in which patients traditionally participate exclusively as research subjects is the engagement of patients in non-traditional roles, defined in the survey as occurring “whenever patients are named as personnel in research projects as advisors, consultants, or investigators where they are involved in any aspect of research from topic development through study design, implementation, interpretation, and dissemination.” Thus, the survey contained a battery of questions about how challenging it was to have patients serve in non-traditional, non-subject research roles (Very, Somewhat, A little, and Not at all challenging). Next, we asked about challenges pertaining to study elements that are frequently (but not exclusively) encountered in PCOR, such as the creation of local registries, multi-site studies, and investigators engaging in research activities for which they are not adequately trained (Figure 1 for full listing).

IRB responsibility, practices, and the need for guidance

We asked chairpersons for their opinions about how much responsibility their IRB had to: a) protect patients serving in non-traditional roles, and b) protect their institution from potential problems arising from patients serving in these roles. Next, we asked whether their IRB considers patients serving in non-traditional roles “to be research subjects even if they are not formally enrolled as subjects in the same study” (yes/no). Because actual policies and

practices may offer insights into IRB behavior, for chairpersons whose IRB had reviewed a PCOR proposal in the last year, we asked how often their IRBs set requirements for patients serving in non-traditional roles to provide informed consent, undergo HIPAA training (training in privacy and security protections for health information) or CITI training (foundational training in human subjects protections), or disclose conflicts of interest (Full list in Figure 2). We also asked whose responsibility it was (e.g., principal-investigator (PI), IRB, funder, patients, research institutions) to ensure that “patients serving in non-traditional roles were adequately trained in human subjects research ethics”. Finally, as a way to determine the usefulness of further developmental work in the area of PCOR-research ethics, we asked respondents to indicate whether federal guidance would be helpful.

Statistical Analysis

We used descriptive statistics including proportions and measures of central tendency and variability to report the sample characteristics as well as other survey responses. Pearson chi square tests were used to evaluate bivariate associations with IRB volume of protocols and experience with PCOR. The volume of protocols at the institution was categorized as low, medium and high based on terciles. All items were stratified by volume and PCOR experience, although we only report stratified results if more than one of the bivariate associations were statistically significant. Survey responses were based on the universe of eligible population; hence the results are not weighted. All statistical tests were two-sided with an alpha of 0.05. Analyses were performed using STATA MP version 14 (STATA Corp. College Station, TX).

RESULTS

Characteristics of the Respondents

Of the 459 IRB chairpersons in the OHRP listing at research intensive institutions, 5 were chosen for cognitive pre-testing, and 18 were excluded due to unknown or missing addresses, leaving a final study sample of 436. Of these, 265 returned a questionnaire, for a response rate of 61%. A majority of IRB chairpersons were male (63%) and white (92%), and 93% were actively serving as chair at the time of the survey (Table 1). The average institutional protocol volume was 843 in the prior year. Approximately 68% of respondents had at least some experience reviewing PCOR submissions. Respondents and non-respondents were similar in terms of their institutional affiliation (Medical School: 60% vs. 62%, respectively; School of Public Health: 27% vs. 21%; and Independent Research Hospitals: 13% vs. 17%) (not in Tables).

Value of PCOR

The majority of respondents were supportive of studies having patients serve in non-traditional research roles (Table 2). Almost all thought this feature was meaningful and important to patients and caregivers (90%), and added value to research (83%); a majority felt it improved the quality of the research process generally (69%), and at their institution specifically (60%). These perceptions did not vary by the volume of protocols. However, chairpersons with PCOR experience were more likely than others to agree or strongly agree that such studies added value to research (87% vs 75%), were beneficial to advancing

science (82% vs 70%), and improved the quality of research at their institution (66% vs 42%) (all $p < .05$). At the same time, a substantial number of respondents agreed or strongly agreed that PCOR protocols, as compared to non-PCOR, were less scientifically sound (27%), and were not adequately thought through with respect to human subject protection issues (46%) (not in tables).

Challenges reviewing PCOR protocols

IRB chairpersons' views of the challenges posed by PCOR varied widely (Figure 1). For example, about $\frac{3}{4}$ or more felt very or somewhat challenged by reviewing PCOR studies in which patients in non-traditional roles had access to identifiable data (84%) or served in dual roles as both subject and researcher (78%); and a majority identified challenges stemming from inadequately trained investigators (73%). By contrast, a minority reported feeling very or somewhat challenged by patients serving on advisory boards (24%) or by the creation of local registries for recruitment (31%). Overall, 61.5% found PCOR protocols more difficult to review as compared with other types of protocols (not in figure).

IRB responsibility, practices, and need for guidance

More than a quarter (27%) of chairpersons reported that their IRB considers patients serving in non-traditional roles to be research subjects even if they were not formally enrolled as subjects in the same study. We found wide variation in IRB requirements for patients engaged in non-traditional roles (Figure 2). For example, 59% and 50%, respectively, said their IRBs always or often required patients to undergo CITI or HIPAA training, while 53% always/often required a conflict of interest (COI) disclosure. A substantial minority always/often required patients in these roles to be listed as study staff (43%), or to provide formal informed consent (37%).

More than half of respondents (60%) felt that their IRB had a lot of responsibility to protect patients serving in non-traditional roles; and 55% felt that the IRB had a lot of responsibility to protect the institution from problems that might be created by such activity (55%) (Table 3). When asked about ensuring that patients in non-traditional roles were adequately trained in research ethics, nearly all placed a lot of responsibility on the PI (97%), with somewhat lower numbers indicating responsibility rested with the IRB (60%), the funder (27%), the patients themselves (49%), and their institutions (48%).

IRB chairpersons were supportive of the need for additional guidance (Table 4). Two-thirds to four-fifths felt it would be very or somewhat helpful for the federal government to provide guidance on the topics listed. Chairpersons from high volume institutions were less likely ($p < .05$) to perceive a need for guidance with respect to training IRB members or informed consent. On the other hand, chairpersons with no PCOR experience were more likely to express a need for guidance with respect to training IRB members, conflict of interest, or policies around the use of electronic health records (all $p < .05$).

DISCUSSION

IRBs review human subjects research protocols – consistent with federal regulations and guidance documents – in order to protect the rights, safety, and well-being of research

participants and ensure the integrity of the research process. However, the rapid advent of patients taking on new, non-traditional roles in PCOR may pose a challenge for IRBs, investigators, and institutions. In order to provide guidance to IRBs, if needed, it is best to first understand their perceptions of whether there are problems with selected research designs. One group of researchers identified potential ethical and regulatory issues with patient-centered research such as consent, risk determination, indirect participation, multi-system review, overlap with quality improvement, and treatment of vulnerable subjects. (Sugarman, 2016) To gain a fuller picture of the perspective of IRBs, we surveyed all IRB chairpersons at research-intensive institutions in the U.S. about their attitudes towards the value of PCOR, the roles and responsibilities of IRBs in review and oversight of PCOR, and the need for guidance. We learned several valuable lessons.

First, IRB chairpersons reported mixed views regarding the value of PCOR. There was a perception by significant numbers of IRB chairpersons that PCOR protocols were less scientifically sound and perhaps not as well thought through as non-PCOR protocols, although chairperson experience with PCOR was associated with increased comfort with these methods. Like other emerging fields, such as CBPR, genetics, or patient safety research, it may take time for both researchers and IRBs to understand the ethical issues and regulatory oversight of newer or blended methods. One important aspect of PCOR is patient involvement, with the possibility that patient research partners are not trained as scientists. While a large majority of respondents felt that this feature is meaningful, it also may raise concerns about ethical and privacy issues and their interpretation within a regulatory framework. Furthermore, because the investigators may be using methods that are less familiar to them (e.g. clinical trialists conducting surveys, focus groups and semi structured interviews), they may not design their study or describe their methods in a manner consistent with what IRBs require, which can hamper the review process. Finally, IRBs in some cases may need guidance on how to fit newer methods to the regulatory and ethical framework under which they operate.

Indeed, these are not merely operational concerns but also ethical ones: if PCOR studies are not well-designed to produce generalizable knowledge, then patients are being asked to give their time (and in some cases incur actual risks) for a study that is less likely to succeed in producing useful results. What is more, funding for research is limited and it is of ethical importance that these resources be appropriately stewarded – both because funding for one study may result in less funding for another, and because the commitment of the public to funding research may sour if it comes to believe that these studies do not generate generalizable knowledge. None of this is to say that PCOR studies are *actually* less scientifically well-designed – indeed the majority of respondents felt otherwise. But it does mean that IRBs may benefit from better understanding PCORI's methodology standards, peer review process, and approach to funding decisions, and PCORI should ensure that scientific concerns are resolved, and investigators understand how best to convey their proposals to IRBs.

Second, there is wide variation in what training, protections, and safeguards IRBs require for patients participating in research in non-traditional roles. This may reflect the fact that the IRB system is, after all, designed to allow for contextual judgment. However, the variation

observed in our study may be reflective of a larger phenomenon of IRB inconsistency resulting from the fact that different studies get reviewed by different boards, all exercising their own discretion within distinct institutional contexts.(Abbott & Grady, 2011) Of course, to the extent different approaches are based on different factual circumstances or case-specific details, variation may be appropriate. What constitutes appropriate protection for patients likely depends on details of the particular non-traditional roles that patient-partners occupy in the context of a specific study. But when like cases are treated differently by IRBs – for example, when one IRB requires patient collaborators to engage in training and sign consent documents while another treats collaborators like investigators – problems are likely to arise regarding fairness, efficiency, and quality. Given respondent views about perceived value of PCOR and difficulty with review and oversight of PCOR, as well as expressed requests for guidance, IRB-level variation suggests the need for clearer standards for how different types of patient roles in research should be handled, what requirements should be imposed, and which safeguards to provide appropriate protections without hindering PCOR. Such guidance can improve consistent treatment of patient partners in research, or help clarify when inconsistent treatment can be justified.

Finally, the fact that nearly a quarter of chairpersons considered patients serving in non-traditional roles to be subjects even when they are not formally enrolled in the study—and therefore are not “human subjects” per the applicable regulatory definition —strongly suggests that some IRBs may be overly protective of patient research partners. This tendency to protect was mirrored by a majority of respondents who also felt the need to protect their institution from PCOR-related problems. We suspect that many concerned with the PCOR oversight accept a form of ‘patient exceptionalism’ whereby safeguards that they would not regard as necessary for traditional study-staff or investigators are thought to be necessary when patients are engaged in these roles. To the extent that patient exceptionalism is justified, safeguards on patient engagement are appropriate. If, however, patient exceptionalism reflects misconceptions about the appropriate scope of the patient role or the vulnerability (or liabilities) of engaged patients, this could have a chilling effect on meaningful participation and thus undermine the benefits that patient engagement in research could provide. Because this is a foundational issue for PCOR – whether the patients are researchers, subjects, or both – PCOR stakeholders should aim for clarity and uniformity.

Limitations

There are several limitations. First, this research may not be generalizable to IRBs working in settings other than research-intensive medical schools, teaching hospitals, or schools of public health. Second, while we were able to determine that non-respondents were similar to respondents on IRB location, it is possible that non-respondents significantly varied from respondents on dimensions only available in the survey such as IRB volume and PCOR experience. Third, it is understood that many IRB decisions are based on the particulars of a given protocol, which may not have been captured with precision in our survey. Although our instrument underwent substantial pre-testing, it may have been challenging for chairpersons to answer general or hypothetical questions, especially in those cases where they had limited experience with PCOR. Fourth, there is no standard definition of PCOR. We tried to overcome this limitation by offering a definition of PCOR in the questionnaire

that we thought was relatively uncontroversial, but we concede that our results may not be generalizable to IRBs using a different definition. Finally, we were unable to determine with certainty whether concerns were influenced by unique aspects of PCOR, logistical issues, or by elements that are present in other kinds of research but simply more common in PCOR. In practice, it may be the intersection of common concerns associated with investigator training or multi-site studies and less familiar issues associated with patients in multiple roles that leads to IRB unease.

Conclusion

We conducted the first national survey of IRB chairpersons about ethical and regulatory oversight issues in PCOR, and found concerns over the value of PCOR, variability in IRB oversight, and possible instances of patient exceptionalism. The involvement of patients in non-traditional roles in research studies is the defining feature of PCOR. Engaging patients in research is proffered to have notable benefits, including exploration of previously unexplored research questions, enhanced recruitment and retention, consideration of previously neglected perspectives, and greater overall relevance to patients' medical decision-making, (Domecq et al., 2014; L. E. Ellis & Kass, 2017b; Frank et al., 2014) which in turn could lead to quicker dissemination of findings and changes to clinical practice. Funding agencies other than PCORI are increasingly encouraging stakeholder engagement. To facilitate the success of PCOR, our findings highlight the need for guidance around ethical and regulatory issues associated with PCOR, with a focus on the multiple roles of patient partners. Although our survey did not ask explicitly about similarities and differences between PCOR and CBPR, to the extent that both types of research engage individuals who would typically participate in research only as subjects, such guidance would likely have broad relevance.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Best Practices

Our conclusions apply to IRB chairpersons in research intensive institutions, and may not apply to other institutions.

Research Agenda

The results of our national survey are meant to inform a national policy discussion about the opportunities and challenges for the ethical and regulatory oversight of PCOR. Our future research will obtain stakeholder consensus around recommendations and guidelines for IRB processes.

Educational Implications

If our study results lead to adoption of national recommendations and guidelines, such material could be used to educate IRB members in their review and oversight of PCOR.

Actual Survey Question: "Please rate how challenging each of the following are for your IRB's review of PCOR protocols"

Figure 1.

Level of challenge in review of PCOR protocols

Actual Survey Question: "Please rate how challenging each of the following are for your IRB's review of PCOR protocols"

Actual Survey Question: "Please think about all of the protocols your IRB has reviewed involving patients in non-traditional roles. How often does your IRB or institution require patients serving in those roles to ...?"

Figure 2.

Participation requirements for patients in non-traditional roles

Actual Survey Question: "Please think about all of the protocols your IRB has reviewed involving patients in non-traditional roles. How often does your IRB or institution require patients serving in those roles to ...?"

Table 1

Characteristics of Respondents

	Number ^I	% or mean (SD)
IRB setting		
Medical School	138	53.1%
SOPH/other University	74	28.5%
Hospital	48	18.5%
Total	260	
Sex		
Male	166	63.1%
Female	92	35.0%
Other	5	2.0%
Total	263	
Race/Ethnicity		
White	238	91.9%
Black	5	1.9%
Asian	8	3.1%
Other	8	3.1%
Total	259	
IRB chair status		
Current IRB chair	241	92.7%
Former IRB chair	19	7.3%
Total	260	
PCOR experience		
None	79	31.6%
Little, Some, or A Lot	171	68.4%
Total	250	
Volume of all IRB protocols		
Mean (sd)	249	843.1 ($\pm$ 1093.7)
Low	88	35.3%
Medium	78	31.3%
High	83	33.3%
Total	249	

^ITotals may vary due to missing data

Table 2

Perceived value of PCOR by IRB chairs

	IRB volume				PCOR Experience			
	Total ^f (n= 249)	Low (n= 88)	Medium (n= 78)	High (n= 83)	p	Total ^f (n= 250)	None at all (n= 79)	Little, Some, or A Lot (n= 171)
<i>Percent strongly agree or agree</i>								
Having patients serve in non-traditional roles....								
a. Is meaningful and important to patients and caregivers	89.8	91.5	91.8	86.4	0.440	89.1	87.5	89.8
b. Adds value to research	83.4	80.5	84.9	85.0	0.754	83.0	74.6	86.7
c. Is beneficial to advancing science	79.6	79.0	82.2	77.8	0.882	78.4	70.4	81.8
d. Improves the quality of the research process	68.6	69.1	66.2	70.4	0.651	67.6	61.6	70.3
e. Improves the quality of research at your institution	59.7	58.2	58.3	62.2	0.927	59.0	42.0	66.1
f. Does not add value to data quality	26.5	28.7	21.7	28.4	0.414	26.3	29.0	25.2
g. Fails to lead to better research outcomes	18.3	19.2	17.9	17.8	0.437	18.6	20.3	17.9

^fTotals may vary due to missing data

Table 3

Perceived responsibility of the IRB

	Percent			
	Number ¹	A lot	Some	A Little None
In general, how much responsibility do you feel your IRB has to protect patients who are serving in non-traditional roles and activities on PCOR studies?	252	59.9	25.8	8.7 5.6
In general, how much responsibility do you feel your IRB has to protect your institution from problems created by patients serving in non-traditional roles on PCOR studies?	251	55.0	29.1	11.5 4.4
Please indicate how much responsibility each of the following groups have for ensuring that patients who are serving in non-traditional research roles on PCOR studies are adequately trained regarding human subjects research ethics				
a. The PI	252	96.8	2.8	0.4 0.0
b. The IRB	251	60.2	34.7	4.0 1.2
c. The research funder	250	27.2	40.0	25.6 7.2
d. The patients themselves	252	49.6	35.7	11.5 3.2
e. The institutions that the IRBs serve	252	48.1	40.5	8.7 2.8

¹Totals may vary due to missing data

Table 4

Perceived desire for IRB guidance from the Federal government

	IRB volume					PCOR Experience			
	All (n= 249)	Low (n=88)	Medium (n= 78)	High (n=83)	p	All (n=250)	None (n= 79)	Little, Some, or A Lot (n= 171)	p
	<i>Percent very or somewhat helpful</i>					<i>Percent very or somewhat helpful</i>			
Potential topics of federal guidance...									
a. Training for PIs regarding IRB issues specific to PCOR research	83.2	85.9	86.3	77.5	0.247	83.4	89.3	80.7	0.096
b. Training for IRB members regarding PCOR related research in general	79.9	85.9	86.5	67.5	0.003	80.2	88.0	76.6	0.041
c. Policies regarding conflicts of interest among individuals serving as both subjects and in non-traditional roles in PCOR	78.1	79.5	80.3	74.7	0.659	78.0	90.5	72.2	0.002
d. Informed consent for patients serving in non-traditional roles	76.5	80.9	82.4	66.2	0.030	77.6	78.7	77.1	0.788
e. Standardization across IRBs in policies/practices related to PCOR research in general	75.3	78.8	81.1	66.2	0.066	75.6	82.7	72.5	0.087
f. Training for patients serving in non-traditional roles	73.6	78.8	74.3	67.5	0.253	74.8	78.7	73.0	0.352
g. Policies related to the use of EHRs in PCOR research	72.1	76.2	71.6	68.3	0.533	73.3	85.1	68.1	0.006
h. Policies related to the participation of patients in grant development activities	65.3	69.4	64.9	61.2	0.544	65.3	72.0	62.3	0.142

Totals may vary due to missing data