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Institutional Review Board Barriers and Solutions Encountered in the Collaboration Among Pharmacists and Physicians To Improve Outcomes Now (CAPTION) Study: a National, Multicenter, Practice-Based Implementation Trial

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Abstract

Study Objective—To categorize institutional review board (IRB) challenges and solutions encountered in a multicenter, practice-based research network (PBRN) study and to assess the impact of IRB requirements on individual principal investigators' (PIs') willingness to participate in future PBRN studies.

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Design—Descriptive analysis of IRB challenges and solutions encountered in the Collaboration Among Pharmacists and Physicians To Improve Outcomes Now (CAPTION) study—a multicenter, prospective, cluster-randomized study conducted by the National Interdisciplinary Primary Care PBRN—and a correlational analysis from a survey of individual site PIs.

Measurements and main results—IRB barriers encountered and solutions were categorized for study sites. A survey of study-site PIs was conducted with a correlational analysis assessing the impact of various IRB requirements and individual PIs' willingness to participate in future PBRN studies; of 31 study sites participating in the CAPTION study, 28 study-site PIs were surveyed. IRBs posed a number of challenges, including bias regarding the source of the application, issues regarding study design, study instruments, access to patient records, study procedures, Spanish-only speaking subjects, role of clinic physicians, interdepartmental concerns, and updates at continuing review. Responses from the PI survey (21 of 28 PIs surveyed [75% response rate]) indicated that the willingness of an individual to serve as a PI in the future was inversely related to the perceived difficulty of obtaining initial ($r_s = -0.599$, $p = 0.004$) and continuing ($r_s = -0.464$, $p = 0.034$) IRB approval.

Conclusion—Significant time and resources were required to address various challenges associated with IRB approval, which negatively impacted an individual PI's willingness to participate in future PBRN projects. A revision of current rules and regulations regarding human subjects protection for practice-based studies, improvement in IRB processes, and support from coordinating centers may decrease the burden associated with IRB approval and increase participation in practice-based research.

Keywords

institutional review board; IRB; barriers; practice-based research network

The vast majority of medical care delivered in the United States occurs in nonacademic, community settings. In fact, 21.7% of individuals who responded to a telephone survey conducted in 2000 had sought care during the previous month in a primary care or specialty clinic, whereas less than 0.01% had been admitted to an academic medical center hospital.¹ Remarkably, this distribution has changed little over the past 40 years.² Considering that the majority of medical research is conducted in academic medical centers, yet most care actually occurs in nonacademic, primary care settings, questions persist regarding the external validity and real-world effectiveness of various interventions.

Practice-Based Research Networks (PBRNs) were developed to bridge the divide between where medical research is conducted and where the results are used in practice.³ The Agency for Healthcare Research and Quality (AHRQ) defines a PBRN as a group of at least 15 primary care practices devoted principally to the care of patients that seeks to “expand the science base of clinical care through systematic inquiry to better understand the health and health care events that unfold daily in their community practice settings.”⁴ Beginning in the late 1970s and 1980s, and with support by the federal government, the number and types of PBRNs have grown significantly, with 162 primary care PBRNs currently registered with AHRQ.^{5, 6}

The National Interdisciplinary Primary Care Practice–Based Research Network (NIPCPBRN) was founded in 2007 with its mission to “study interdisciplinary team–based care of chronic medical conditions, with emphasis on the development of strategies to improve national guideline adherence.”⁷ Over the past four years, the NIPC-PBRN has been engaged in a large, national, cluster-randomized effectiveness trial—the Collaboration Among Pharmacists and Physicians to Improve Outcomes Now (CAPTION) trial—evaluating a team-based approach to care involving a physician and pharmacist in the management of hypertension or asthma that could be scaled up and implemented on a larger scale.⁸ The CAPTION study has encountered multiple challenges associated with the institutional review board (IRB) approval process. IRB review and approval is critical to ensure that human research is conducted in an ethical manner and that patient rights and safety are protected. However, the regulatory challenges posed by multicenter research projects can often be daunting. Although IRBs have a common set of rules and regulations that must be followed,⁹ the interpretation and implementation of these regulations can be extremely variable. Several studies on multicenter research have documented significant variability among IRBs on a wide range of issues including study classification (e.g., exempt vs. expedited vs. full IRB review),¹⁰⁻¹⁴ variations in consent requirements,¹⁰⁻¹⁸ methods and/or issues related to subject recruitment,^{10, 17, 18} and length of time for approval.^{10, 12, 14, 17, 18} These differences result in significant administrative burdens when conducting multicenter research, particularly with regard to staff time and resources. A recent study assessed the variability in IRB reviews for a multicenter, minimal-risk study of financial incentives for evidence-based hypertension care that involved 25 Veteran Affairs medical centers. It was estimated the time spent on administrative approval was 6,729 hours and cost approximately \$168,000 in staff salaries.¹⁴

While previous studies have described various challenges related to the IRB approval process for multicenter studies, scant data are available that describe individual site principal investigator (PI) opinions related to this process.¹⁹ The goal of the current study is to describe IRB barriers encountered and to provide a correlational analysis regarding the impact of various IRB administrative requirements and individual PIs’ willingness to participate in future PBRN studies.

Methods

In this study, we describe the IRB challenges and resolutions encountered in the CAPTION study and provide a correlational analysis of PI perceptions related to the IRB process and willingness to participate in future PBRN projects. The CAPTION trial has been described elsewhere.⁸ Briefly, 27 family medicine clinics, later expanded to 31 clinics with 28 PIs, that employed clinical pharmacists located in 14 states were stratified, then randomized, to one of 3 groups: 9-month physician-pharmacist collaborative model (PPCM) arm (n=216), 24-month PPCM arm (n=216), or control group (n=216) that also included a distracter intervention for asthma. The primary outcome measure for the study was to determine if the PPCM model would lead to improved blood pressure or asthma control. Secondary outcomes included comparison of blood pressure control among minorities (54% of the BP study population) and those from lower socioeconomic groups, and the association between blood pressure control rates and provider attitudes to the PPCM model.

IRB approval was sought and granted from the primary sponsor recipient (University of Iowa, Iowa City, IA). IRB submission material and forms (e.g., protocol, consent templates, recruitment letter templates) were provided to collaborating investigators who sought IRB approval through their own institutions. Research staff at the University of Iowa monitored the approval process and documented regulatory issues or concerns from individual IRBs when they occurred, as well as solutions or resolutions to encountered problems.

Next, all study PIs (n=28) were invited to complete an anonymous, 15-item Web-based survey (Inquisite Survey, Austin, TX). The authors, who have significant experience in IRB-related issues, developed the survey tool (e.g., content validity). Opinions regarding level of difficulty with initial and continuing IRB approval, willingness to serve as a study PI or as a collaborating investigator in a subsequent research endeavor, and general attitudes regarding the IRB process and workload were assessed on a 5-point Likert scale (5=strongly agree, 4=agree, 3=neutral, 2=disagree, 1=strong disagree). In addition, basic demographic data including type of position, prior experience as a PI, job expectations for research and/or scholarship, administrative research support, type of IRB and submission system, and estimated time required for initial and continuing review were obtained. Opportunities for additional comments or opinions were provided as free-text fields. The Texas Tech University Health Science Center Institutional Review Board (Amarillo, TX) approved the survey study.

Statistical Analysis

Types of IRB barriers encountered and resolutions related to initial IRB approval and first continuing review approval were collected and categorized by the primary sponsor recipient. Data from the Web-based surveys were downloaded as a comma-separated values (CSV) file. Data were then imported to SPSS software, version 19 (SPSS Inc., Chicago, IL) for analysis. Descriptive statistics were used to describe PI and IRB characteristics. Spearman's correlation coefficient was used to compare all variables related to perceived level of difficulty in obtaining initial and continuing IRB approval, willingness to participate again in the CAPTION trial as either a PI or collaborating investigator, perceptions related to navigating the IRB process, availability of research support, past experience as a PI or co-PI, type of IRB system (e.g., computer- vs. paper-based), and estimated time spent on initial and first continuing IRB approval. The Mann Whitney U test was used to determine whether type of IRB (i.e., both university and hospital/health system versus others) was associated with the time required for initial or continuing IRB approval and willingness to participate in a future PBRN study.

Results

The CAPTION study received funding by the National Heart, Lung and Blood Institute effective 4/15/2009 for both the Clinical Coordinating Center (CCC) and the Data Coordinating Center. Each of the medical offices that agreed to serve as a performance site for the study received a subcontract from the primary university. Each medical office named a local site PI, lead physician, pharmacist (if not also the PI), and a study coordinator. Many of the study coordinators were employees of the medical office and were assigned by the

office to recruit and consent subjects and collect data as part of their clinic responsibilities. Several university departments had research office staff that filled the study coordinator position.

The CAPTION study was approved by the primary study sponsor's IRB on 06/10/2009. Submission materials and forms (e.g., protocol, consent templates, recruitment letter templates) were distributed to the original subcontracted study sites (n=27) between 2/13/2009 and 5/9/2009. The first subcontracted study site received IRB approval on 4/10/2009 and the last on 12/28/2010. Due to challenges with IRB approvals that, in part, delayed patient recruitment and enrollment, sites were expanded to a total of 31 sites with 28 PIs. The final newly added site received IRB approval on 4/27/2011. The study enrolled the last patient (n=750) on March 29, 2012, approximately 9 months later than planned. These delays and requirements for adding sites had major budget implications for the CCC.

Characteristics of the CAPTION study PIs and IRBs, as well as the estimated time spent on the initial IRB submission and the first continuing review, are shown in Table 1. Respondents were predominantly affiliated with an academic institution (95.2%), and the position held by most respondents (90.5%) included an expectation for research and/or scholarship. The majority of respondents (71.4%) used a computer-based IRB system, and only a minority of respondents (19.0%) had administrative support for assisting with the IRB process.

During the initial IRB submission as well as the first continuing review, a number of diverse and disparate issues arose with various subcontracted study sites (Table 2). These included issues related to bias regarding the source of the application, study design, assessment instruments, access to patient records, study procedures, Spanish-only speaking subjects, role of site researchers and physicians, interdepartmental or administrative concerns, questions regarding updates to site operations manuals, and delays in providing researchers with updated consent documents.

The perceptions of subcontracted study sites (site PIs) related to the level of difficulty with initial and first continuing IRB approval, willingness to participate in future PBRN studies as either a PI or collaborating investigator (non-PI), and amount of time initially anticipated for navigating the IRB process are shown in Table 3.

A correlational analysis was conducted to determine if associations existed between any of the variables obtained from the survey of CAPTION study PIs. Bivariate analyses yielded a number of significant correlations, particularly with regard to the perceived level of difficulty in obtaining initial IRB approval, level of difficulty associated with the first continuing review, willingness to serve again as a PI, and willingness to participate in a future PBRN study due to the IRB process (Table 4).

Availability of research support was not associated with perceived difficulty in obtaining initial or continuing IRB approval, or with willingness to either serve again as a site PI or participate in another PBRN study in the future. However, the more research projects that an individual had served on as a PI or co-PI, the less IRB procedures dissuaded the PI from participating in a PBRN study in the future ($r_s = 0.531$, $p = 0.016$). The perceived level of

difficulty in obtaining initial IRB approval was greater for those with computer-based systems than for those with paper-based systems ($r_{RB} = 0.589$, $p = 0.005$).

The type of IRB (i.e., both university and hospital/health systems vs. others) was not associated with the perceived difficulty required for initial or continuing IRB approval, or with the willingness of an individual to participate in a future PBRN study (Mann Whitney U, $p > 0.05$ for all 3 tests). The type of IRB was not associated with estimated hours spent on initial or continuing IRB approval (Mann Whitney U, $p > 0.05$ for both tests).

Discussion

Navigating the IRB process during the CAPTION study was much more challenging and time consuming for the participating site PIs than expected, even for more seasoned investigators who had been involved with many prior research studies. In fact, many of these barriers would likely not be limited to PBRN-focused research. However, despite the effort and challenges encountered in the current PBRN study, most of these investigators would still agree to participate in the CAPTION trial if invited again. This latter finding may have been due to the fact that centralized staff at the CCC prepared IRB templates, assisted with navigating the IRB process for newer investigators, and helped address the numerous questions and issues raised by the 28 IRBs. It is likely that if this centralized support were not available, many investigators would be less likely to participate in the future. It should be noted that very few studies conducted in PBRNs have the finances to support the infrastructure developed for the CAPTION trial, whose substantial budget was funded by the NIH. These identified IRB barriers and issues required a great deal of time for the CCC staff, and streamlining the IRB process could reduce these large budgetary requirements.

A unique aspect of the current study is that a formal analysis was conducted to assess if correlations existed between various factors associated with the IRB process and PI characteristics and perceptions. Interestingly, despite a relatively low number of study PIs (21 of 28 surveyed [75% response rate]), several correlations were significant. The greater the difficulty in obtaining initial and continuing IRB approval, the less willing the individual was to serve as a PI in the future. More generally, the willingness of an individual to serve in any capacity on any future PBRN study was inversely related to the perceived difficulty of obtaining both initial ($r_S = -0.511$, $p = 0.021$) and continuing ($r_S = -0.824$, $p < 0.001$) IRB approval. While others have identified IRB challenges as barrier for participating in PBRN research^{19, 25}, scant data are available formally assessing PI perceptions.¹⁹ These findings are concerning, considering the great need for continued and expanded research assessing different models of care, particularly in the primary care setting and involving traditionally underrepresented patient populations.

A potential solution to many of the IRB hurdles encountered in multicenter studies, whether through a formal PBRN or outside of a PBRN, is the use of a central IRB. In July 2011, the Office of the Secretary of the Department of Health and Human Services and Office of Science and Technology Policy issued an advance notice of proposed rulemaking for comment related to human research subjects protection,²⁶ with the opportunity for comment extended to October 26, 2011.²⁷ One of the proposed rules being considered was mandating

that all domestic multicenter studies rely on a single IRB as the IRB of record. Solicitation for comments and recommendations specifically related to this proposed rule included advantages and disadvantages of mandating a single IRB for multicenter studies as opposed to “encouraging” how local IRB review either adds or detracts from human protections and institutional views and ethics, legal liability, inefficiencies of local IRB review of multicenter studies, and methods by which an IRB of record would be selected.²⁶ Final decisions regarding the proposed rules are currently pending.

Experience with the CAPTION study identified several solutions to overcoming barriers and delays in the IRB approval process. Depending on the level of budgetary support given to a study’s central coordinating team, additional strategies for improving success with IRB processes associated with any PBRN study, beyond those used in the CAPTION study, would include the following:

- Set a series of deadlines for a preliminary draft of the IRB application, final submission, and IRB approval. Send reminders of those deadlines and inform sites that those that fail to meet the schedule of deadlines will be dropped. Sites that have substantial difficulty meeting these deadlines are likely to have difficulty meeting other study requirements.
- Consider having several additional clinics in reserve or as alternates that can be quickly added if initial sites or their IRBs have unacceptable delays in approval.
- Schedule one or more conference calls with the individual at each site who is working on the initial IRB application. During the call, review drafted IRB materials and devise an early strategy to deal with potential problems.
- If the study includes oversight by study monitors from the data coordinating center, these monitors should be included on the local IRB forms to facilitate examination of medical records during monitoring site visits. Have each site obtain IRB approval for both the study coordinator and the monitor from the CCC to have full access to subject medical record data. Have sites explicitly include this as a condition of participation in the study.
- Select study principal investigators with a track record of successful research. Seasoned investigators will likely have significantly more experience navigating the IRB process and dealing with various barriers.

There are limitations with this analysis of IRB challenges associated with the CAPTION study. First, the vast majority (95.2%) of PIs who responded to the PI survey had an academic appointment and research and/or scholarship as an expectation of their position. Thus, the external validity of some of the findings may be questioned. However, the distribution of primary care study sites across the country and inclusion of minorities and underserved patient populations strengthen the study’s external validity. It is likely that there would be even greater barriers in settings not affiliated with academic settings and with PIs who have not conducted previous research. This finding questions whether the hope for PBRNs to include true community-based medical offices can be realized if these IRB challenges remain. Second, a formal systematic process for tracking time and effort required for IRB approvals was not conducted a priori. Thus, it is possible that errors and/or

inaccuracies may exist in some responses obtained from the PI survey. Despite these limitations, the study findings corroborate many perceptions related to challenges with multicenter studies and IRB approval noted previously in the literature.^{10–18}

Conclusion

A number of challenges related to local IRB approval were encountered during the CAPTION study. These included bias regarding source of application, issues relating to study design, study instruments, study procedures, access to patient records, Spanish-only speaking subjects, role of clinic physicians, interdepartmental concerns, and problems at the time of continuing review. Most issues or concerns were adequately resolved. However, the time and resources required to do this decreased the willingness of some site PIs to participate in future PBRN projects. This is an unfortunate finding in an era where research evaluating different forms of health care delivery in a primary care setting is sorely needed. Moreover, challenges with local IRBs can add considerable cost to practice-based research at a time when federal agencies have difficulty funding such studies and can also delay progress with the overall progress of the study. Hopefully, proposed rule changes regarding protection of human subjects in community-based research will make conducting PBRN studies less arduous from an IRB perspective, especially for inclusion of nonacademic practice sites.

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Table 1Characteristics of the CAPTION study PIs and IRBs^a

Characteristic	Value
Position type	
Academic	20 (95.2)
Nonacademic	1 (4.8)
Had research and/or scholarship expectation for current position	19 (90.5)
Number of research projects involved with as a PI or co-PI	
< 5	9 (42.9)
5-10	7 (33.3)
11-20	3 (14.3)
> 20	2 (9.5)
Had administrative support for assisting with IRB process	4 (19.0)
Had computer-based IRB system	15 (71.4)
Type of IRB	
University	6 (28.6)
Hospital/Health system	2 (9.5)
Both University and Hospital/Health System	12 (57.1)
Community	1 (4.8)
Estimated time spent on initial IRB application (hours)	20 ± 16.4* (range 0-50)
Estimated time spent on first continuing review application (hours)	5 ± 4.5* (range 0-20)

Data are no. (%) of respondents or mean ± SD values.

^a21 of 28 PIs surveyed responded.

* Estimated time required for each PI to complete the IRB process; does not include the time required by the staff at the CCC to assist the local PIs.

Table 2

Types of IRB barriers encountered and resolution for the 31 study sites

IRB site number [*]	Barrier Description	Resolution [†]
<i>Bias regarding source of application</i>		
1	IRB reluctant to approve because application submitted by a pharmacist and not a physician or centralized research team.	Pharmacist PI formed an alliance with member of IRB and worked with that individual to resolve multiple issues on application.
<i>Study design issues</i>		
2	Documentation requested for the NIH grant peer review process, including NIH reviewer comments.	Award notice dates for grant submission, revision, and NIH funding submitted. Primary grant recipient refused to send reviewer comments. The IRB acquiesced.
3	Specific details regarding the analysis plan requested.	A two-page summary document of the statistical analysis plan was created by the University of Iowa Clinical Coordinating Center (CCC) and site submitted to the IRB.
<i>Instrument issue</i>		
4	IRB judged that the Short Portable Mental Status Questionnaire (SPMSQ) was "biased" because African-Americans have a racially-defined alteration to their score.	Original published manuscript describing standardization and validation of the SPMSQ, which included modified and validated scoring for African American subjects, was sent to the IRB. IRB would still not approve scoring; this one site was required by their IRB to <i>not</i> decrease scores for African American subjects, potentially making it more difficult for African Americans to pass SPMSQ.
<i>Issues with access to patient records:</i>		
5, 6	Reluctant to give study coordinator access to patient records since s/he is not a clinic employee.	IRB 5 eventually gave the study coordinator access to medical records. IRB 6 required that clinic staff generate an initial list of patients who meet specific study criteria. Those patients were grouped according to provider, and each list of names was sent to the provider for approval. The approved list was provided to the study coordinator so that he could review the pulled data and mail invitation letters. Study coordinator never had access to medical records and relied on clinic personnel to pull data for him. This requirement greatly increased the burden on local clinic staff.
<i>Issues with study procedures:</i>		
7	The IRB did not permit the local study coordinator to mail out letters of invitation.	The study coordinator created each draft personalized letter and forwarded it to IRB staff, who recreated each letter as a stamped PDF and returned it to the study coordinator for mailing.
8, 2	IRBs did not want to permit local site investigators to call patients who did not return a response postcard. IRB 2 used two different committees to review the two study arms; the first committee to review the study approved use of the phone call, the second committee did not approve the	IRB 8 refused to let sites make follow-up phone calls to nonrespondents, interpreting lack of a response as a decision to not participate. The two clinics working under this IRB failed to meet their enrollment targets, largely because they were unable to call subjects. The objecting committee for IRB 2 approved the procedure after study investigators presented a detailed argument in favor of the procedure and pointed out the discrepancy in committee opinions.

IRB site number*	Barrier Description	Resolution [†]
	recruitment strategy.	
9	Because pregnancy is an exclusion criterion, the IRB asked researchers to either screen for pregnancy or require double-barrier birth control method.	Site researchers informed the IRB that the exclusion was imposed due to regulations placed on pregnant women serving as research subjects, not due to any anticipated potential for harm. The IRB accepted the explanation and required no further action.
8, 10	The IRBs requested clarification about the activities of study monitors from the centralized Data Coordinating Center.	The CCC provided more detail including the affiliation of the study monitor and, for IRB 8, the names of the monitors.
10	The IRB asked to see all materials used for patient education.	The site's IRB application was modified to state that the pharmacist would use educational tools typically used in practice.
<i>Issues related to use of Spanish-only speaking subjects:</i>		
10, 11	The IRBs required documentation of certification for the individual who translated English consent documents into Spanish. IRB 11 also required a translator's invoice anytime a change was made to an approved recruitment document	The CCC provided sites with the certification document and with a copy of the invoice.
1	IRB required the site to identify specific "designated interpreters" who would be added to the IRB application	The clinic worked with the hospital interpreting office to identify a single interpreter who completed human subjects education and was approved by the IRB. Visits for Spanish-only speakers were scheduled on days that interpreter was available.
12	The IRB required creation of a script for interpreters so that there would be consistency in how the interpreters asked questions for Spanish-only speakers.	The certified translator for the CCC translated all survey questions into Spanish, and the site provided those translated forms to their IRB.
<i>Issues with role:</i>		
12	The IRB asked for a detailed description of the physician role in the study.	Site researchers detailed the procedures for pharmacist-physician interactions when the pharmacist recommended a change in therapy.
12	The IRB required site researchers to devise a method that allowed clinic physicians to opt out of being part of the study intervention.	Site researchers provided clinic physicians with contact information for the CCC so that physicians could notify the coordinating center if they did not wish to participate.
12	The IRB asked for detailed information on the content of training sessions and educational activities for site researchers and clinic physicians.	The CCC drafted a summary statement, and the site researchers provided this information to their IRB.
<i>Interdepartmental issues:</i>		
10	The IRB would not approve until legal/corporate office reviewed and approved the study.	Site researchers waited until approval was given by the legal/corporate office.

IRB site number [*]	Barrier Description	Resolution [†]
12	After the IRB approved the project, the budgeting office had to sign off before enrollment could begin.	Site researchers waited until approval was given by the budgeting office.
13	IRB approval took >12 months. The research team was unable to invoice for year 1 pre-enrollment activities because of delay in approval.	Site had to wait for IRB approval before submitting an invoice for year 1 activities.
14, 15	The IRB required that the project name on the IRB application exactly duplicate the project name on the subaward agreement from the University of Iowa.	The site researchers submitted an IRB amendment to change the project title on the IRB application.
<i>Issues at the time of continuing review:</i>		
16	The IRB questioned updates to the manual of operations, asking if changes to the IRB application needed to be approved.	Site researchers informed the IRB that the changes represented either greater clarification or different arrangement of content, with no changes in procedures that had not already been approved by the IRB.
4	The IRB delayed 58 days after approving the continuing review application before providing site investigators with a new stamped and dated informed consent document.	Site could not enroll subjects during the time that they did not have a current dated informed consent document.

* Study site numbers were randomized and deidentified.

† All resolutions were adequate and protocol approved unless otherwise indicated.

Table 3Results from the PI Survey^a

Statement	Level of agreement
Obtaining initial IRB approval for the CAPTION study was difficult.	3.0 (3.0)
Obtaining continuing IRB approval for the CAPTION study was difficult.	2.0 (1.0)
If invited to participate in the CAPTION study again as a site PI, I would participate.	5.0 (1.5)
If invited to participate in the CAPTION study again, but as a collaborating investigator and not a site PI, I would participate.	4.5 (1.0)
The IRB process would not dissuade me from participating in a future PBRN research study.	4.0 (2.5)
Navigating the IRB process was more time consuming than I had anticipated.	4.0 (2.5)

Data are median (interquartile range) values of responses indicated on 5-point Likert scale: 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree.

^a21 of 28 PIs surveyed responded; not all respondents answered all questions.

Table 4

Significant correlations among survey questions

Survey Questions	Correlation (Spearman correlation coefficient)	p-value
<i>"Obtaining initial IRB approval was difficult"</i> correlated with:		
Obtaining continuing IRB approval was difficult	0.713	<0.001
Would serve again as site PI	−0.599	0.004
IRB process would not dissuade me from a future study	−0.511	0.021
IRB process more time consuming than anticipated	0.711	<0.001
IRB application is computer-based	0.589	0.005
Time in hours spent on initial application	0.454	0.039
<i>"Obtaining first IRB continuing review approval was difficult"</i> correlated with:		
Would serve again as PI	−0.464	0.034
IRB process would not dissuade me from a future study	−0.824	<0.001
IRB process more time consuming than anticipated	0.464	0.034
Time in hours spent on first continuing review	0.517	0.016
<i>"I would serve again as site PI"</i> correlated with:		
Would serve as a collaborating investigator	0.722	<0.001
IRB application is computer-based	−0.480	0.028
<i>"The IRB process would not dissuade me from participating in a future PBRN study"</i> correlated with:		
IRB process more time consuming than anticipated	−0.591	0.006
Number of research projects involved with as PI or co-PI	0.531	0.016
Estimated hours spent on the initial IRB application	−0.444	0.05
Estimated hours spent on first continuing review application	−0.535	0.015