Institutional review board and regulatory solutions in The Dental PBRN

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Abstract

Objectives: Effectively addressing regulatory and human participant protection issues with Institutional Review Boards (IRBs, or ethics committees) and grants administration entities is an important component of conducting research in large collaborative networks. A dental practice-based research network called "DPBRN" (http://www.DPBRN.org) comprises dentists in two health maintenance organizations, several universities, seven US states, and three Scandinavian countries. Our objectives are to describe: a) the various human participants and regulatory requirements and solutions for each of DPBRN's five regions; b) their impact on study protocols and implementation; and c) lessons learned from this process.
Methods: Following numerous discussions with IRB and grants administrative personnel for each region, some practitioner-investigators are attached to their respective IRBs and contracting entities via sub-contracts between their organizations and the network's administrative site. Others are attached via Individual Investigator Agreements and contractually obligated via Memoranda of Agreement.
Results: IRBs approve general operations under one approval, but specific research projects via separate approvals. Various formal IRB and grants administrative agreements have been arranged to customize research to the network context. In some instances, this occurred after feedback from patients and practitioners that lengthy written consent forms impeded research and raised suspicion, instead of decreasing it.
Conclusions: Instead of viewing IRBs and institutional administrators as potentially adversarial, customized solutions can be identified by engaging them in collegial discussions that identify common ground within regulatory bounds. Although time-intensive and complex, these solutions improve acceptability of practice-based research to patients, practitioners, and university researchers.

Introduction

Practice-based research networks (PBRNs) have continued to grow in number (1–4), and more recently have included dental PBRNs (5–7). However, this unique research context can present some regulatory challenges when conducting research studies. Some literature does exist on the challenges of meeting Institutional Review Board (IRB) and regulatory requirements for multi-center studies, including PBRNs (8–12). However, to our knowledge, no literature exists on the challenges of obtaining approval from IRBs to conduct research in the dental PBRN context, nor any regarding the mechanisms to meet grants administration regulatory requirements. Such information and "lessons learned" from others who have developed a dental PBRN should be helpful to those who plan to develop a comparable network.

All federally-funded human participants research conducted in the United States must be reviewed and approved by an IRB. The US Federal Policy for the Protection of Human Subjects applies, which is also known as the "Common Rule" (13). Through its Federal-wide Assurance Number, an institution commits that it will comply with the Common Rule. IRBs generally also take responsibility for ensuring that researchers follow proper procedures to ensure the privacy of information that patients provide. These procedures must be consistent with the Privacy Rule and the Security Rule in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (14). Within the regulatory limits framed by the Common Rule, the Privacy Rule, the Security Rule, and certain other regulations, IRBs are given wide latitude.

Although dental care has much in common with medical care, because dental care and its remuneration are driven by doing procedures, rather than by emphasizing diagnostic and non-surgical activity, this can have implications for IRB and regulatory review. Therefore, we explicate herein the human participants protections and regulatory issues faced in the dental PBRN context and describe practical solutions from one dental PBRN called "The Dental Practice-Based Research Network" (DPBRN).

Materials and methods

We have discussed previously the development of the DPBRN (5). The DPBRN central administrative base is at the University of Alabama at Birmingham (UAB) and contains both the Network Chair administrative group and the Coordinating Center. There are five DPBRN regions: Alabama/Mississippi, Florida/Georgia, Minnesota, Permanente Dental Associates, and Scandinavia.

All DPBRN studies must be approved by its Executive Committee. Studies are then sent for final scientific review to the DPBRN Protocol Review Committee, whose members are selected by the National Institute of Dental and Craniofacial Research and who are unaffiliated with DPBRN, so as to provide an objective, independent scientific review. If approved, DPBRN then submits IRB applications from each region for review of human participants protections.

Practitioner enrollment comprises completing an online questionnaire that describes practitioner and practice characteristics. Practitioners who wish to participate in clinical studies are required to attend an orientation session or a video version of it, for which they receive continuing education credit.

Results

Procedures required to participate in clinical studies

In addition to faculty investigators and staff being required to obtain certification in human participants research, all practitioner-investigators are required to complete a course and submit documentation to their Regional Coordinator. The most common course is available online (15). Typically, practitioner-investigators review a printed version supplied by DPBRN, log onto the web site, take a test to document competency, print and save electronically a certificate, and then e-mail that to their Regional Coordinator.

DPBRN regions and the Coordinating Center obtain IRB approval for general network operations, such as recruitment, communications, enrollment data, and related activities. Specific research projects are approved via separate, study-specific IRB approvals. Practitioner-investigators can participate in studies only after an IRB has approved their participation for a specific study. Thus, each practitioner-investigator is added to each study separately, on a study-by-study basis. To be added to a particular study, practitioner-investigators must complete additional requirements, with some variation by region, as shown in Table 1.

Practitioner-investigators in the Alabama/Mississippi region sign a study-specific amendment to a study already-approved by the UAB IRB (Table 1). Additionally, they sign an informed consent form for practitioner-investigators because the UAB IRB determined that practitioner-investigators are both subjects of the research and study investigators for most DPBRN studies. Most studies require that practitioner-investigators administer the informed consent to patients and collect data from patients; in this role, they are investigators. However, some of these same studies also require practitioner-investigators to record their opinions or recommendations about that treatment with the objective of observing whether the dentist's treatment or opinions change over time. Because the main goal of DPBRN research is to improve daily clinical practice, DPBRN is interested in

Table 1 IRB and Grants Administration Mechanisms for Most DPBRN Clinical Studies

DPBRN Region	IRB location	Personnel	Mechanism to attach personnel to their IRB
Alabama/ Mississippi*	University of Alabama at Birmingham	Practitioner-investigators in Alabama and Mississippi	Practitioner-investigator signs: • Study-specific amendment to a study already approved by the University of Alabama at Birmingham IRB. • Study-specific practitioner-investigator Informed Consent Form approved by the University of Alabama at Birmingham IRB. • Individual Investigator Agreement with the University of Alabama at Birmingham IRB and grants administration. • Memorandum of Agreement with the University of Alabama at Birmingham with a study-specific amendment. • Statement of Financial Conflict of Interest.
		Network Chair Group investigators and staff employed by the University of Alabama at Birmingham	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the University of Alabama at Birmingham IRB. Human participants protection and conflict of interest statements are handled institutionally with the University of Alabama at Birmingham as a university employee, consistent with university policy.
		Coordinating Center investigators and staff employed by the University of Alabama at Birmingham	Named as participating in the study when a study-specific Coordinating Center IRB application is submitted to the University of Alabama at Birmingham IRB. Human participants protection and conflict of interest statements are handled institutionally with the University of Alabama at Birmingham as a university employee, consistent with university policy.
Florida/Georgia	University of Florida	Practitioner-investigators in Florida and Georgia	Practitioner-investigator signs: • Study-specific amendment to study already approved by the University of Florida IRB. • Study-specific practitioner-investigator Informed Consent Form approved by the University of Florida IRB. • Individual Investigator Agreement and Confidentiality Statement with the University of Florida IRB. • Memorandum of Agreement with the University of Alabama at Birmingham with a study-specific amendment. • Statement of Financial Conflict of Interest.
		Network Chair Group investigators and staff employed by the University of Florida	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the UF IRB. Human participants protection and conflict of interest statements are handled institutionally with the University of Florida as a university employee, consistent with university policy.
Minnesota	HealthPartners Research Foundation	Practitioner-investigators employed by HealthPartners	Named as participating in the study when a study-specific Network Chair Group IRB amendment is submitted to the HealthPartners Research Foundation IRB. Human participants protection and conflict of interest statements are handled institutionally with the HealthPartners Research Foundation as an employee, consistent with HealthPartners Research Foundation policy.
		Practitioner-investigators in Minnesota	Practitioner-investigator signs: • Study-specific amendment to study already approved by the HealthPartners Research Foundation IRB. • Study-specific practitioner-investigator Informed Consent Form already approved by the HealthPartners Research Foundation IRB. • Individual Investigator Agreement with the HealthPartners Research Foundation IRB • Memorandum of Agreement with the University of Alabama at Birmingham with a study-specific amendment. • Statement of Financial Conflict of Interest.
		Network Chair Group investigators and staff employed by the HealthPartners Research Foundation	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the HPRF IRB. Human participants protection and conflict of interest statements are handled institutionally with the HealthPartners Research Foundation as an employee, consistent with HealthPartners Research Foundation policy. Also, a Data Use Agreement is signed between HealthPartners Research Foundation and the University of Alabama at Birmingham.

Table 1 *Continued*

DPBRN Region	IRB location	Personnel	Mechanism to attach personnel to their IRB
Permanente Dental Associates	Kaiser Permanente Northwest	Practitioner-investigators employed by Permanente Dental Associates	Named as participating in the study when a study-specific Network Chair Group IRB amendment is submitted to the Kaiser Permanente Northwest IRB. Human participant protection and conflict of interest statements are handled institutionally with Kaiser Permanente Center for Health Research as a Permanente Dental Associates employee, consistent with Kaiser Permanente Research Foundation policy.
		Network Chair Group investigators and staff employed by the Kaiser Permanente Research Foundation	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the Kaiser Permanente Research Foundation IRB. Human participants protection and conflict of interest statements are handled institutionally with Kaiser Permanente Research Foundation as an employee, consistent with Kaiser Permanente Research Foundation policy. Also, a Data Use Agreement is signed between the Kaiser Permanente Research Foundation and the University of Alabama at Birmingham.
Scandinavia/ Denmark	The University of Alabama at Birmingham IRB serves as the IRB of record for minimal-risk studies	Practitioner-investigators in Denmark	Practitioner-investigator signs: • Study-specific amendment to a study already approved by the University of Alabama at Birmingham IRB. • Study-specific practitioner-investigator Informed Consent Form approved by the University of Alabama at Birmingham IRB. • Individual Investigator Agreement with the University of Alabama at Birmingham IRB and grants administration.
		Network Chair Group investigator and staff at the University of Copenhagen paid as University of Alabama at Birmingham consultants	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the University of Alabama at Birmingham IRB.
Scandinavia/ Norway	Ethics Committee for the eastern region of Norway	Practitioner-investigators in the southeast region of Norway	Practitioner-investigator: • Document completion of training in human participant research.
		Network Chair Group investigator	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the University of Alabama at Birmingham IRB.
Scandinavia/ Sweden	Ethics Committee for the southern region of Sweden	Practitioner-investigators in the southern region of Sweden	Practitioner-investigator: • Document completion of training in human participant research.
		Network Chair Group investigator	Named as participating in the study when a study-specific Network Chair Group IRB application is submitted to the University of Alabama at Birmingham IRB.

*One Dental Practice-Based Research Network (DPBRN) practitioner-investigator in the Alabama/Mississippi region provides dental care only in an American Indian tribally-owned facility. This required separate review and approval by the US Indian Health Service Institutional Review Board (IRB), to which that practitioner-investigator is attached.

knowing which methods are effective in changing and improving treatment methods. This requires that DPBRN observe practitioner-investigators' behavior over time and that we inform them that we are doing so. In this role, they are research participants, not investigators.

Practitioner-investigators are attached to the UAB IRB via an Individual Investigator Agreement, a mechanism allowed by the agency responsible for oversight of US federally-funded studies (16). A sample agreement is provided at the agency's web site. This agreement documents that the practitioner-investigator understands, has received approved training for, and agrees to comply with policies and procedures for the protection of human participants in research. Similar procedures are used for practitioner-investigators in the Florida/Georgia region, except that they are attached to the University of Florida IRB (Table 1). The UAB IRB requires documentation that all practitioner-investigators have been approved to conduct the study by the applicable IRB before the UAB Network Chair Group and Coordinating Center can accept data from that practitioner-investigator.

To create a mechanism to remunerate practitioner-investigators for the time required to do studies, practitioner-

investigators in the Alabama/Mississippi and Florida/Georgia regions sign a Memorandum of Agreement in which they agree to fulfill all the obligations of the study (Table 1). This agreement is subsequently amended for each study. In addition to specifying data collection and remuneration schedules, it constitutes a contract in which the practitioner-investigator agrees to terms required of all institutions awarded federal grants by the National Institutes of Health (17). It also has statements about complying with HIPAA (14) and other federal requirements. To specifically meet documentation requirements that there is no conflict of interest, practitioner-investigators who are not employed by an institution must also sign a document to certify statements about financial conflict of interest.

Requirements differ depending on whether the practitioner-investigator is an employee of a DPBRN organization. Permanente Dental Associates and HealthPartners practitioner-investigators, who are employees of their respective organizations, are named as investigators when an IRB application for a specific study is submitted. Consequently, they do not have to sign study-specific amendments, individual investigator agreements, or memoranda of agreement. The same circumstance applies to faculty investigators and staff who are employees of DPBRN-affiliated research foundations or universities. Practitioners in Minnesota who are in private practice and not HealthPartners employees, are attached to the HealthPartners Research Foundation IRB in a manner similar to practitioners in other regions (Table 1).

For observational studies with minimal risk, the UAB IRB serves as the IRB of record for Danish practitioner-investigators. Therefore, Danish practitioners follow procedures identical to practitioner-investigators in the Alabama/Mississippi region, except that because they are remunerated for studies from a contract with the University of Copenhagen, and thus do not sign a Memorandum of Agreement or Statement of Conflict of Interest with the UAB. As DPBRN ultimately does randomized clinical trials with non-behavioral, clinical outcomes (i.e., studies that are not minimal risk), it is anticipated that Danish practitioners will be attached to a Danish IRB.

As institutional entities, both the Kaiser Permanente Center for Health Research and the HealthPartners Research Foundation provide data to the DPBRN Coordinating Center. They do so only after study-specific Data Use Agreements have been signed, so as to contractually obligate UAB and these two foundations to handle and disseminate the data in a mutually agreed-upon manner.

Regional variation in informed consent requirements for clinical studies

Following its first network-wide study that involved all five regions – a questionnaire about caries diagnostic and treatment methods – DPBRN began its first network-wide clinical study ("Reasons for Placing the First Restoration on Permanent Tooth Surfaces"), requiring practitioner-investigators to collect data about patients during the course of actual treatment. The study recorded the clinical circumstances and characteristics of restorations placed on previously-unrestored tooth surfaces. The study did not alter treatment. Instead, it recorded information about routine dental treatment that was going to be done anyway. To reduce the number of IRB reviews required for each project, DPBRN first approached IRBs in each region to determine if they would accept review by one or more of the other DPBRN IRBs. No IRB granted such a request. Consequently, we next submitted study applications to each region's IRB.

Requirements to do the "Reasons for Placing . . ." study (Table 2) varied across DPBRN's IRBs. Following face-to-face discussion between the IRB and the investigative team, the HealthPartners Research Foundation IRB approved a waiver of documentation of informed consent because the study involved routine treatment that would occur anyway and which was not affected by the research. Also, dentists, not patients, were viewed as the research subjects. For the Alabama/Mississippi region, a protocol was submitted using an informed consent form that was standard for most UAB projects (Table 2). Early feedback from practitioner-investigators and patients using these forms was that this process was cumbersome, inconsistent with the notion that this was a minimal-risk study of routine treatment, and raised suspicion among patients instead of decreasing it. Following discussions with the UAB IRB Office, a revised protocol was submitted and approved. In the revised protocol, participants were provided a one-page information sheet, the study was discussed with them, informed consent was obtained verbally, and documentation of consent was noted in the patient's chart and a study log of enrolled participants. A comparable reduction in the length of the consent process was also obtained with the Kaiser Permanente Northwest IRB (Table 2) after a similar, two-iteration process. Also, paperwork burden was reduced substantially when clinic staff was not required to make copies of signed consent forms in the clinic. In the Florida/Georgia region, DPBRN re-applied to that region's IRB and obtained authority to reduce considerably the informed consent form (Table 2). The genesis for this second-iteration application was the lessons learned from interacting with the UAB IRB on that study.

An IRB in one of the DPBRN regions had a concern that remunerating practitioner-investigators for participating in clinical studies may affect the treatment that they provide or provide an incentive to do more treatment – thus, potentially creating a conflict of interest that would not be in the patient's best interest. We explained that practitioner-investigators are not remunerated for doing a treatment procedure – a

Table 2 Institutional Review Board (IRB) Process and Results from the First Five-Region, Network-Wide Clinical Study in The Dental Practice-Based Research Network (DPBRN)

DPBRN Region	Process and result
Alabama/Mississippi*	• First iteration: University of Alabama at Birmingham IRB approves a six-page Informed consent Form and a one-page HIPAA form, which the patient signs. • Feedback from Alabama/Mississippi DPBRN practitioners and patients doing the study suggests that the informed consent process for this study is very cumbersome and creates suspicion. DPBRN then submits an application to the University of Alabama at Birmingham IRB for a revised protocol. The HIPAA form is revised to adapt it to the PBRN context, from its earlier default version that was written for the hospital and university research environment. • Final iteration: University of Alabama at Birmingham IRB approves a one-page Patient Information Sheet that is given to the patient. Informed consent is obtained verbally with documentation by the practitioner-investigator in the patient's chart and study log that informed consent was obtained.
Florida/Georgia	• First iteration: University of Florida IRB approves a nine-page Informed Consent Form and one-page HIPPA form, which the patient signs. • Results from the University of Alabama at Birmingham IRB re-application described above creates openness to further revision. The Florida/Georgia region submits an application for a revised protocol to the University of Florida IRB. • Final iteration: University of Florida IRB approves a two-page Informed Consent Form that the patient signs.
Minnesota	• First iteration: Following face-to-face discussions with the IRB in advance of the IRB application, HealthPartners Research Foundation IRB approves a waiver of documentation of informed consent because the study involves routine treatment that will be done anyway.
Permanente Dental Associates	• First iteration: Kaiser Permanente Northwest IRB approves a four-page Informed Consent Form with modified HIPAA language. The patient signs both forms. • Final iteration: Kaiser Permanente Northwest IRB approves a two-page Informed Consent Form with a carbon copy attached so that the patient can be given a copy at the time of signature.
Scandinavia/Denmark	• First iteration: The Danish ethics committee for the applicable region of Denmark concludes that research of this type is not under its purview and refers it to the Danish Data Protection Agency. • Second iteration: The Data Protection Agency approves the study, but the University of Alabama at Birmingham IRB cannot accept its finding because this agency does not have a Federal-wide Assurance Number. • Third iteration: The Danish region re-applies to the ethics committee, which makes the same conclusion as before. • Fourth iteration: A telephone conference call is held between the Danish ethics committee and the University of Alabama at Birmingham IRB. The Danish ethics committee sends a letter to the University of Alabama at Birmingham IRB confirming its approval of the study as a result of its review for "local context" and that it is willing for the University of Alabama at Birmingham IRB to serve as the IRB of record for the study and other minimal-risk observational studies. • Final iteration: DPBRN submits a revised application to the University of Alabama at Birmingham IRB, asking it to serve as the IRB of record for Danish practitioner-investigators. University of Alabama at Birmingham procedures apply with "local context" taken into account.
Scandinavia/Norway	• First iteration: The Norwegian ethics committee declined to send a letter to the University of Alabama at Birmingham IRB confirming that it approved of the study protocol. • Second iteration: The Norwegian ethics committee for the applicable region of Norway concludes that research of this type is not under its purview and the Norwegian Data Protection Agency accepts the finding of the Danish Data Protection Agency without any further review. • Third iteration: A re-submitted application is reviewed and approved. • Fourth iteration: A revised application to use a verbal informed consent process is reviewed and approved.
Scandinavia/Sweden	• First iteration: The Swedish ethics committee declined to send a letter to the University of Alabama at Birmingham IRB confirming that it approved the study protocol. • Second iteration: The Swedish ethics committee for the applicable region of Sweden concludes that research of this type is not under its purview and the Swedish Data Protection Agency accepts the finding of the Danish Data Protection Agency without any further review. • Third iteration: A re-submitted application is reviewed and approved. A verbal informed consent process is included in that application.

*HIPAA = Health Insurance Portability and Accountability Act.

procedure that would be done anyway regardless of whether the patient consents for the research – but instead are remunerated for the extra time that it takes to record data about that procedure. With this understanding, the IRB granted approval.

Most institutions have standard HIPAA authorization forms that must be included with the participant's informed consent form, which participants are asked to sign. Typically, these forms were written with the hospital or academic health center context in mind, not the PBRN outpatient

dental office context. This was the case for the UAB form. Initial contact with the UAB administrative office led to our being informed that this form was the one that had to be used, and that no one had ever asked to use a different version because the form's wording was the result of many interactions over many months with legal, regulatory, and administrative sections on campus. Nonetheless, we were told that a revision could be requested if appropriate input and approval from the office of the university legal counsel was obtained in written form. Following discussion with the legal office – a discussion which was neither lengthy nor burdensome – revised language was approved. This revised or eliminated language improved the acceptability of the form substantially, because the language was customized to an outpatient, dental context.

The process to obtain IRB approval for Danish practitioner-investigators lasted more than a year (Table 2). Because the "Reasons for Placing . . ." study was a minimal-risk study, the applicable Danish IRB referred its review to the Danish Data Protection Agency, which approved the study. The Danish ethics committee had a US Federal-wide Assurance number, but the Danish Data Protection Agency did not. Therefore, the UAB IRB could not accept its review. This ultimately led to a conference call between the Chair of the Danish Ethics Committee, the Principal Investigator of the DPBRN Scandinavian region, the Chair of the UAB IRB, the Director of the Office of the UAB IRB, and the DPBRN Network Chair Group. The end result was an agreement that the UAB IRB would serve as the IRB of record for the Danish practitioner-investigators when those studies were minimal-risk and following a Danish review for "local context" – meaning that the study procedures were deemed consistent with local norms and capabilities.

As in Denmark, the Norwegian and Swedish practitioner-investigators are clustered in a geographic area covered by one Norwegian IRB and one Swedish IRB. The "Reasons for Placing . . ." study was reviewed and approved by both of these IRBs. A request to handle informed consent verbally, similar to the situation in the Alabama/Mississippi region, was approved as a second iteration with the Norwegian IRB. However, because the Swedish IRB did not have a current Federal-wide Assurance Number, this required a subsequent formal written agreement between the Swedish and UAB IRBs.

Discussion

The PBRN research context presents unique challenges. Unlike studies conducted in academic health centers, PBRN studies are conducted by clinicians in community-based settings, by persons who may be doing their first research study. Understandably, administrative entities need to have written, contractual assurance that these personnel understand and will comply with all applicable regulations. Federal regulations governing these assurances have continued to evolve. Indeed, the Individual Investigator Agreement mechanism itself is only from 2005 (16). Unique to the PBRN context, a healthy tension exists between needs to conduct research directly relevant to daily clinical practice, protect confidentiality, provide informed consent, minimize burden on practitioner-investigators and their patients, while making it all work in a single research project across different regional clinical settings with different IRB requirements.

In addition to human participants assurances, a mechanism is necessary to remunerate practitioner-investigators, to contractually obligate them to follow appropriate regulations, to assure no conflict of interest, and related matters. This mechanism is handled by the Memorandum of Agreement, in addition to the Statement of Financial Conflict of Interest. Although this is quite a bit of work for DPBRN faculty and staff, practitioner-investigators, and IRBs and grants administration entities, the arrangements are surmountable.

Establishing the required formal relationships between practitioner-investigators and IRBs was a process that lasted more than a year. In almost all cases, the greatest progress occurred only after holding face-to-face meetings between the respective IRBs and investigators and staff in the Network Chair Group. Unfortunately, for most regions, these meetings occurred only after a protracted exchange of written documents, telephone calls, electronic mails, and in some cases, misunderstandings – a process that could have been shortened if initial contact had comprised a single face-to-face meeting of all involved parties. Therefore, our recommendation is to engage both the IRB and grants administration entities in face-to-face meetings very early in the process. We strongly recommend that representatives from all three areas of responsibility (IRB, grants administration, and dental PBRN administration) attend these meetings at the same time. It was not unusual for representatives from these three groups to be in need of education about the regulatory requirements or how they might best be applied to the dental PBRN context. That is, having joint face-to-face meetings provided a valuable venue for all parties involved to become educated about all the perspectives and understandings of all the other parties.

The outpatient dental office has a mix of personnel that includes dentists, dental hygienists, dental assistants, and other office types of office personnel. The practitioner-investigators must be the ones to confirm that the participants understand all aspects of the study and are fully informed before they sign the informed consent form. However, other office personnel are allowed to explain the study to potential participants and to answer questions about it – if they are certified in human participants research. Office personnel who have not been certified are only allowed to provide an information sheet or a copy of the informed consent form to read as background before the potential participant discusses the

study with the practitioner-investigator. Therefore, each DPBRN practice is asked to consider whether it wants to have certain non-dentist staff certified in human participants research, and if it does, DPBRN facilitates that. Having other personnel trained increases efficiency because most questions that potential participants ask can be easily answered by these trained personnel.

In common with multi-center study research contexts in general, PBRNs face many challenges with obtaining IRB and regulatory approvals (10,11,18–22). In response, several options have been proposed to streamline the IRB process – the most common of which has been proposals for a single, central IRB that would review all studies for the PBRN. Although such an arrangement should be a step forward, a central IRB would still most likely want to have review by local IRBs for "local context" to take into account any social or cultural aspects of local populations. Use of single, central IRB was not feasible in DPBRN because none of the regional IRBs would cede its authority to another IRB. Nonetheless, the central IRB approach continues to garner national attention (21) and may one day be a feasible alternative. Additionally, even if multiple IRB reviews are required, it would be helpful if all IRBs would use the same application forms and application procedures (20).

As the literature about variation in IRB reviews for multicenter studies would suggest (10,11,20), our dental PBRN context also experienced IRB variation. Nonetheless, substantial streamlining of protocols did result from engaging DPBRN IRBs in discussion. Instead of viewing IRBs and grants administrators as potentially adversarial, customized solutions can be identified by engaging them in collegial discussions that identify common ground within regulatory bounds. These solutions can improve acceptability of PBRN research to patients, practitioners, and university researchers. Dental PBRNs can play an active role in these advancements, showing that knowledge transfer not only happens in the research-to-practice direction, but also in the practice-to-research direction.

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