



National Dental PBRN Handbook

FOR PRACTITIONERS AND RESEARCHERS

Disclaimer: This document has a version number and applicable date because specific content is subject to change.

CHR 60561 04/16/2020

Copyright © 2020 National Dental PBRN

Introduction to the Handbook

There has never been a better time to work in the field of oral health. Ever-improving technology, an increased focus on medical-dental integration, and new knowledge are improving the health of patients across the United States.

Behind all of it is research— and that’s where we come in.

In 2005, the National Institute of Dental and Craniofacial Research (NIDCR), part of the U.S. National Institutes of Health, supported the creation of three regional dental practice-based research networks. In 2012, NIDCR provided another 7 years of funding, folding those initial groups into one large nationwide network called the National Dental Practice-Based Research Network (National Dental PBRN). During that period, dozens of studies were conducted in practices and conferences were held in regions spanning the United States.

Now, with the next round of NIDCR funding, the National Dental PBRN will undertake new office-based studies, increase our membership, and seek new ways to engage dental practitioners in the network.

Whether you are a member already or are considering membership, we hope this handbook proves useful. You’ll find information on the network, its regions, participation options, and a user’s guide for proposing and conducting studies.

Sincerely,

Gregg Gilbert
Mary Ann McBurnie

National Dental Practice-Based Research Network



Gregg Gilbert, DDS, MBA
National Network Director



Mary Ann McBurnie, PhD
Network Coordinating
Center Director

Contents

NETWORK OVERVIEW	5
Mission, Vision, and Goals	5
Team Approach to Science	5
Network History	5
Accomplishments	6
Network Structure	7
<i>Regional and Specialty Nodes</i>	7
NETWORK PARTICIPATION	9
Becoming a Member	9
How do I enroll?	9
Participation Options	10
<i>Level 1: Information only</i>	10
<i>Level 2: Limited participation</i>	11
<i>Level 3: Full participation</i>	11
RESEARCHER GUIDE	12
Overview	13
<i>Team approach to science for researchers</i>	13
<i>Research topics for the PBRN context</i>	13
<i>Study design</i>	13
Propose a network questionnaire, pilot or clinical study	14
Obtaining Study development resources from the National Dental PBRN	15
<i>Initial review process and confidentiality of the submitted information</i>	16
<i>Information for developing proposal budgets and budget justifications</i>	16
<i>National Dental PBRN Administrative & Resource Center (ARC)</i>	16
<i>Network Coordinating Center (NCC)</i>	17
Conducting the study	18
<i>Your Grant Is Funded – Now What?</i>	18
<i>Protocol/Study Development</i>	18
<i>Practitioner Recruitment and Engagement</i>	18
<i>Protocol Training</i>	19
<i>Patient Screening, Recruitment, and Consent</i>	19
<i>Data Collection</i>	20
<i>Network Publications and Presentations of Study Results</i>	20
RESOURCES	21



“Talking about network activities with new dentists gave me the opportunity to be a mentor to them, possibly associate with them, and hear their concerns.”

—Dental Practitioner



NETWORK OVERVIEW

Founded in 2005, the National Dental PBRN involves dental practitioners from across the United States who wish to gain knowledge about and engage in clinical research that leads to improved clinical care.

- Mission, Vision, and Goals
- Team Approach to Science
- History
- Accomplishments
- Structure

Network Overview

MISSION, VISION, AND GOALS

The National Dental PBRN is a network of practices and clinics whose members, while principally dedicated to the oral health care of patients, also investigate research questions with practical impact on the quality of dental care. As of March 2019, nearly 7,000 U.S. and internationally based dental practitioners, office staff, and researchers were members of the network.

Mission: To improve oral health by conducting research based in dental practices and by serving dental professionals and their patients through education and collegiality.

Vision: To lead the field of dental practice-based research and to foster dental collegiality.

Goals: We aim to provide practical science about, in, and for the benefit of real-world clinical practice by:

- Conducting national oral health studies that are important to practitioners and their patients with minimal impact to dental office operations and patient flow.
- Strengthening the knowledge base for clinical decision-making.
- Providing evidence to improve routine dental care.
- Improving the integration of dental and medical care.
- Facilitating the movement of the latest evidence into routine clinical practice.

TEAM APPROACH TO SCIENCE

Team science is defined as a collaborative effort to address a scientific question that leverages the strengths and expertise of professionals trained in different disciplines. National Dental PBRN investigators adhere to this approach in conducting clinical studies by working in multidisciplinary groups that engage multiple stakeholders such as academicians, private practitioners, statisticians, project managers, policy makers, and NIDCR representatives in the research and scientific process.

The network's team approach to science relies on the principles of efficiency, productivity, trust, and overall effectiveness. Team members share common objectives, coordinate their resources, and compose a shared agenda of activities to achieve study objectives. Teams agree to meet regularly, define a vision and set goals, communicate effectively, and share data and credit for their research accomplishments.

NETWORK HISTORY

The National Dental PBRN had its start in 2005 when the National Institute of Dental and Craniofacial Research (NIDCR) supported a seven-year grant to establish three regional, independent dental practice-based research networks. In 2012, NIDCR provided funding for another seven years to establish the National Dental Practice-Based Research Network, to include all U.S. states and territories. The network subsequently received funding for another cycle running from 2019-2026.

DISCOVER MORE

[Network and Practice-Based Research: Orientation Video](#)

[Network Publications and Presentations.](#)

Previous [Network Studies](#)

ACCOMPLISHMENTS

In 2019, over 6,000 U.S. dentists and dental hygienists were enrolled in the network. Since 2005, network researchers and practitioners have conducted 38 studies involving nearly 44,000 patients. The studies have supported the publication of over 160 peer-reviewed manuscripts and over 225 conference presentations. Practitioners have been co-authors on nearly 70 percent of publications and presentations. Network members have produced over 1,150 non-peer-reviewed articles and presentations. These activities serve an important role in putting research into practice.

Studies Completed Since 2012

- Anterior Openbite Treatment
- Common Practices of Head & Neck Examinations in U.S. Dental Offices
- Cracked Tooth Registry Study
- Decision Aids for the Management of Suspicious Occlusal Caries Lesions
- Factors for Successful Crowns Clinical Study
- Factors for Successful Crowns Questionnaire Study
- HPV/Risk for Oral Cancer (ROCS) Study
- Isolation Techniques Used When Performing Root Canal Treatment
- Leveraging EDR Data for Clinical Research
- Management of Dentin Hypersensitivity
- Management of Painful TMD
- Multi-Risk Assessment in the Dental Office
- Predicting Root Canal Treatment Outcomes
- Prophylactic Use of Antibiotics in the Dental Office
- Quit Advisor DDS Smoking Cessation Study
- Reducing Prescription Opioid Misuse
- Understanding Dental Information Networks

2005

- NIDCR awards Northwest PRECEDENT, the Dental Practice-Based Research Network, and the PEARL Network 7-year grants to establish a PBRN in their respective regions.


2012

- A single network, the National Dental Practice-Based Research Network is established. All 50 states and U.S. territories are divided into 6 regions, each with a regional administrative site.
- The network presents its first webinar "Prevalence of Questionable Occlusal Caries Lesions."


The nation's network
2013

- Practitioner Advisory Committees (PACs) are formed in each region.
- The network is featured in the March 2013 issue of the ADHA magazine Access.
- The first network symposium is held at AADR in Seattle, WA.


2014

- The network launches and completes its first questionnaire study on isolation techniques and achieves an 88% response rate.
- The IADR/AADR launches an affiliate membership component to serve clinicians involved in PBRNs.
- The network launches its first clinical study, a longitudinal study on cracked teeth.
- The National Dental PBRN Central IRB is established.

2015

- The network launches its first specialty study for orthodontists, the Anterior Openbite Study.
- The network collaborates with investigators on a clinical study via a public/private NIH grant partnership.
- A Department of Defense clinic is the first U.S. military entity to participate in and complete a clinical study.

2016

- The network launches its first study examining the use of electronic dental records.
- The network launches its first study exclusively utilizing electronic data collection.


2017

- The network debuts the Research UPDATES series.



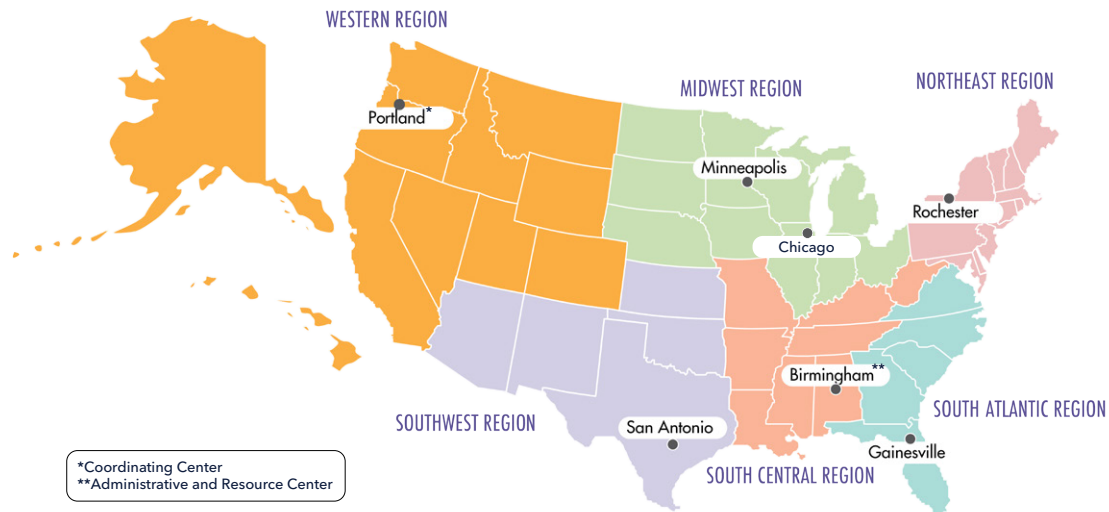
- The network is featured in the ADA News.

2019

- The National Dental PBRN is awarded another 7-year grant by NIDCR.
- The network nomenclature and organizational structure are changed. "Regions" become "Nodes" and "Specialty" and "Patient Population" nodes are added.



NETWORK STRUCTURE



Regional and Specialty Nodes

The National Dental PBRN spans all 50 states and U.S. territories, and comprises six regional nodes and a specialty node. A patient population node will be created in the future. Each node has a local administrative site at an academic center or research institution. The network's Administrative and Resource Center is at the University of Alabama at Birmingham in Birmingham, Alabama, and its National Coordinating Center is at the Kaiser Permanente Center for Health Research in Portland, Oregon.



Jeffrey Fellows
Node Director

Western Region Node - Alaska, American Samoa, California, Colorado, Guam, Hawaii, Idaho, Montana, Nevada, Northern Mariana Islands, Oregon, Utah, Washington, and Wyoming. Administratively based at the Kaiser Permanente Center for Health Research in Portland, Oregon.



Brad Rindal
Node Director

Midwest Region Node - Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. Administratively based at the HealthPartners Research Institute in Minneapolis, Minnesota.



David Cochran
Node Director

Southwest Region Node - Arizona, Kansas, New Mexico, Oklahoma, and Texas. Administratively based at the University of Texas Health Science Center at San Antonio in San Antonio, Texas.



Gregg Gilbert
Node Director

South Central Region Node - Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Tennessee, and West Virginia. Administratively based at the University of Alabama at Birmingham in Birmingham, Alabama.



Valeria Gordan
Node Director

South Atlantic Region Node - Florida, Georgia, North Carolina, South Carolina, and Virginia. Administratively based at the University of Florida in Gainesville, Florida.



Cyril Meyerowitz
Node Director

Northeast Region Node - Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, US Virgin Islands, and Vermont. Administratively based at the University of Rochester in Rochester, New York.



Veerasathpurush Allareddy
Node Director

Specialty Node - Supports dental specialty research and related activities across the network. Administratively based at the University of Illinois at Chicago.



“Providing continuing education credits has been a nice benefit. I really enjoy the meetings where I can interact with other network members.”

—Dental Practitioner



NETWORK PARTICIPATION

The National Dental PBRN serves dental professionals who wish to stay apprised of current dental research and, if they desire, take part in activities ranging from conferences to dental office data collection. This section offers information on participation.

- Becoming a Member
- Participation Options
- Getting 'Study Ready'

Network Participation

BECOMING A MEMBER

What are the benefits of joining the network?

- Contribute to the development of knowledge that improves oral health
- Expand your knowledge base for making clinical decisions
- Meet and interact with other practitioners involved in the network
- Enhance the image of your practice
- Conduct research in your practice
- Engage your staff in the excitement of discovery and quality improvement
- Earn free continuing education (CE) credits
- Receive financial remuneration for the time spent doing studies
- Participate in the dissemination of study results
- Receive newsletters and other information about practice-based research

INTERNATIONAL PARTICIPATION

We welcome participation by our international colleagues as Level 1 enrollees, see page 10.

HOW DO I ENROLL?

Enrolling in the network is easy: The enrollment questionnaire takes approximately 10-20 minutes to complete. You'll need to provide:

- Your name, preferred email, contact phone number, mailing address
- Your primary occupation (practitioner type, student, retired or non-practitioner)
- Desired participation level (1, 2, or 3)
- How you heard about the network
- Information about you, your practice, and your patients

We collect certain information about you and your patients at enrollment so that we can:

- Describe the characteristics of network practitioners and patients in reports and publications
- Make comparisons to the US dental practitioner and patient populations
- Improve the representativeness of practitioner and patient populations in network studies
- Efficiently account for selected practitioner and practice characteristics on study outcomes

We do not share private practice and patient health information that could be used to identify you or your patients without consent. All research activities are reviewed and approved by a central IRB.

Visit the network [homepage](#) and click the Enroll Now link.

Staff at the regional centers across the nation will be your connection to the network. Once you have completed the enrollment process you will be contacted by a regional coordinator about next steps.

PARTICIPATION OPTIONS

Network members select one of three levels of participation depending on their interest in the activities offered. Please note that all activities are voluntary. For example, Level 3 members are not required to participate in a clinical study if the topic is not of interest or the required activities are not a good fit for the practice setting. Members may also change their participation level at any time. The activities available to practitioners at each participation level are summarized below.

ACTIVITIES	LEVEL 1: Informational	LEVEL 2: Limited	LEVEL 3: Full
Receive Information and Updates	✓	✓	✓
Participate in Quick Polls	✓	✓	✓
Suggest a Study Topic	✓	✓	✓
Attend Network Meetings		✓	✓
Participate in a Questionnaire Study		✓	✓
Participate in a Clinical Study			✓
Participate in Network Committees			✓

Level 1: Information only

Level 1 members receive periodic information from the network, including research results, upcoming meetings and studies, Quick Polls, and other pertinent information. This group includes active practitioners, dental office staff who are not involved with direct patient care, practitioners who no longer see patients, researchers, policymakers, and individuals living outside the U.S.

Receive periodic information about upcoming meetings, new research results, education and training opportunities, and other information that may be of interest to them and to patients. Information is shared through email, although the network also uses Facebook, Twitter, and other social media.

Receive information about upcoming studies. All members receive general information about upcoming studies. This helps keep members informed of research activities and provides eligible Level 1 practitioners an opportunity to change their participation level if a study topic is of interest.

Participate in “Quick Polls.” Network members periodically receive email requests to participate in brief surveys (3-5 questions) on a particular topic. Quick Polls are meant to gauge members’ interest in or broad understanding of a topic.

Suggest a study topic. Member practitioners have been a valuable source for study topics within the network and it is part of our mission to conduct research that is important to dental professionals. Practitioners may suggest study topics and clinical questions during practitioner meetings, webinars, and conferences, and via email and other personal communications. Network staff are continually seeking new ways to promote practitioner involvement in the network’s research agenda.

Level 2: Limited participation

Level 2 members receive Level 1 information and may attend network meetings, participate in questionnaire studies, and suggest study topics. Level 2 members include U.S. dental practitioners (dentists, hygienists, assistants, therapists) who provide patient care at least one day per week.

Attend network meetings. Level 2 members can attend network-sponsored national and regional meetings, usually at reduced costs. National meetings may include network symposia in conjunction with the American Association for Dental Research annual conference and practitioner meetings involving members from multiple regional nodes. Level 2 members may also attend practitioner meetings conducted by their regional node staff.

Participate in questionnaire studies. Level 2 practitioners may be invited to participate in scientific survey research conducted by network study teams. In these studies, they are the subject of the research, so no additional network training is required. Participants are typically recruited by email sent from the study team or a regional staff member.

Level 3: Full participation

Level 3 members receive Level 1 & 2 benefits and may participate in clinical studies and network committees. Level 3 members include U.S. dental practitioners (dentists, hygienists, assistants, therapists) who provide patient care at least one day per week.

Participate in clinical studies. Level 3 practitioners can participate in clinical studies in their dental offices. This involves consenting patients in their offices to participate in research and recording data from or about their patients during or outside of office visits. Practitioners and dental office staff are provided relevant training in human subjects protection, research compliance, and study activities.

Participate in network committees. Regional and specialty Nodes have a Practitioner Advisory Committee (PAC) that serves as a clinical resource for the node staff and performs other activities as needed, such as helping develop regional meeting agendas. PACs meet periodically via conference call. A practitioner from each Node serves on a national Practitioner Executive Committee (PEC). This committee provides a critical practitioner voice to the network and input on the relative importance of various clinical topics, practical issues related to dental office implementation of study interventions and research processes, and guidance to study teams during the protocol development stage. PEC members also serve as a liaison for their regional/specialty node colleagues for the national network.

BECOMING 'STUDY READY'

If you choose to participate at Level 3, you can expect to:

- Be contacted by your regional coordinator, who will provide information about studies and gauge your interest
- Complete network trainings and paperwork (human subjects, financial conflict of interest), sign W9 and other legal documents required by each region.
- Study protocol trainings take about 60 minutes.



“I really enjoyed leading a National Dental PBRN study. We learned a great deal about how to operationalize study activities within varying clinic flows. Having network coordinators on the study team helped us avoid and mitigate numerous challenges.”

—Study Principal Investigator

RESEARCHER GUIDE

National Dental PBRN researchers and study teams play a vital role in determining study scope, design, and data collection. To support their efforts, the network helps them tailor studies to network specifications as well as with resources to aid them in developing a study idea for network clinical studies, member surveys, and pilot studies. This section offers the following information for researchers and study teams on preparing and conducting a network study.

- Overview
- Develop proposal budgets
- Propose a network survey, pilot or clinical study
- Conduct the study
- Obtain proposal development resources

OVERVIEW

The network provides vital support to dental researchers and practitioners who conduct oral health research on a wide range of topics. Network studies are funded by NIDCR, primarily through a National Dental PBRN-related Funding Opportunity Announcement (FOA). Oral health researchers and practitioners interested in conducting network-affiliated clinical studies must participate in the NIH grant submission and peer-review process. Guidance and network resources are available to researchers and study teams interested in preparing a grant application for clinical studies conducted in the National Dental PBRN. This section of the Handbook can be used by researchers to help tailor the study scope, design, and data collection strategies to fit the dental PBRN context.

Team approach to science for researchers

The National Dental PBRN advocates a team-science approach, the purpose of which is to leverage the strengths and expertise of professionals in different disciplines. This approach is motivated by lessons learned during 14 years of conducting collaborative research involving oral health researchers, dental practitioners, and professional organizations in the identification, development, conduct, and dissemination of scientific research.

Network studies are conducted by teams that include investigators with diverse skills and knowledge necessary to study implementation. Study teams also include network researchers, practitioners, programmers, and data and clinic coordinators with practical expertise in the design and implementation of clinical research in dental offices. Team members share common objectives, coordinate resources, and compose a shared agenda of activities to achieve study objectives. Network staff provide a variety of contextual guidance that enhances the efficiency and productivity of the study and helps build trust with network participants.

Designing and conducting research in dental offices is challenging. Network staff help study teams efficiently and effectively navigate the unique features and issues germane to this unique form of research. In addition, study teams can tap into network stakeholder groups that can facilitate a wide range of research dissemination and implementation opportunities.

Research topics for the PBRN context

The National Dental PBRN has sponsored research on a wide range of clinical topics in a variety of subject areas (e.g., screening and diagnostic services, dental treatment and management, specialty care, behavioral health). NIDCR funding enables the network to financially support investigator-initiated clinical research that is deemed meritorious following NIH peer review. Grant proposals that are most likely to receive funding address topics that fit within [NIDCR priorities](#) and are relevant to everyday dental practice.

Studies on topics relevant to routine dental practice are the cornerstone of clinical research conducted within the National Dental PBRN. Such research can reduce the time between scientific discovery and widescale adoption in routine dental practice. In addition, study topics with wide practitioner appeal engender enthusiasm among practitioners and their staff to:

- Complete network and study-related trainings to participate in a clinical study
- Screen and recruit patients within a short enrollment window
- Complete study-related activities and data collection activities with minimal oversight
- Participate in post-study data interpretation and dissemination activities

Study design

Research conducted in working dental offices is different than studies conducted in academic settings. Time and resource constraints limit the scope of clinical studies, restrict data collection to essential and readily available measures, and necessitate simplified eligibility/exclusion criteria. Study recruitment and data collection processes must be flexible to account for different practice settings and workflows. Researchers should focus on strategies that minimize the impact on clinic operations and workflow while maintaining the study's scientific integrity. Manuscripts describing lessons learned from previous network studies are available in the Resources section of the Handbook.

The network has sponsored observational cohort studies, case-control studies, and clinical trials. To date, most of the studies have employed an observational cohort design to evaluate current screening, diagnostic, and/or treatment practices in a variety of real-world settings. While preferred on scientific grounds, clinical trials are more challenging to integrate into dental office workflows and may require additional buy-in from practitioners and their staff due to additional training and trial monitoring requirements. In general, researchers should propose the strongest research design that is appropriate, acceptable and feasible to answer the research questions.

When choosing an approach, researchers should consider the following:

- Can the study question be addressed using retrospective or prospective observational data?
- If a clinical trial is proposed, can the unit of analysis be at the practitioner or clinic level?
- Can the study be conducted by dental practitioners within the flow of routine dental care?
- Are participant enrollment and data collection processes flexible enough to accommodate different clinic workflows?
- Can important study data be collected outside of the practitioner-patient visit time (e.g., before or after a visit, in the waiting area, or outside of an office visit)?

Additional considerations:

- Network studies are typically national in scope, involving all of the six regions. For clinical studies, research teams will enroll about 25-30 practitioners in each region and each practitioner will enroll about 25-40 patients. These numbers can vary by region and by practitioner depending on variations in the numbers of eligible practitioners and patients in a region, the frequency of the procedure/service being investigated, and other factors.
- Electronic data capture – via tablets, smart phones, and/or desktop computers – is the primary means of collection for network studies.

PROPOSE A NETWORK QUESTIONNAIRE, PILOT OR CLINICAL STUDY

Researchers interested in conducting studies in the network must submit a research application through an open National Dental PBRN Funding Opportunity Announcement (FOA). Network-related FOAs are released periodically. Open announcements are available on the [NIDCR clinical trials webpage](#) and include submission and review guidelines. Currently, NIDCR provides funding through one of two mechanisms, depending on the type of study:

- UG3/UH3 for clinical trials and large clinical observational studies involving data collection from practitioners and their patients
- XO1 for small developmental/exploratory, feasibility (pilot), and/or questionnaire studies of practitioners and/or patients

Review the FOA of interest for the maximum award project period.

Please note the following:

- Researchers may submit proposals without contacting NIDCR program officials or National Dental PBRN staff.
- Network resources are available to help Study PIs/teams who are interested in proposing a study to be conducted within the National Dental PBRN.
- Study PIs do not have to wait for a network-related FOA to be released in order to obtain study development resources.
- Study PIs do not have to wait for a network-related FOA to be released in order to obtain proposal development resources.

OBTAINING STUDY DEVELOPMENT RESOURCES FROM THE NATIONAL DENTAL PBRN

Researchers interested in obtaining network resources (staff support) are encouraged to follow the steps listed below, which are also listed on the [NIDCR clinical trials webpage](#) under **For Dental Professionals: National Dental Practice-Based Research Network**.

Click on [Researchers Proposing a Study Idea](#) and follow these steps:

1) Download and review the Menu of National Dental PBRN Resources available to all potential applicants

Study PIs/teams can request any or all the following resources that are relevant to the proposed study. Study PIs should request resources as early as possible to allow enough time for relevant network staff to complete requested activities well in advance of the grant application submission date. The following resources are available:

- **Node Director** - Applicants can receive up to 5 hours of consultation services (**We recommend requesting this resource FIRST**)
- **Biostatistician/epidemiologist** - Up to 15 hours
- **Psychometrics expert** - Up to 10 hours
- **Data/study manager** - Up to 5 hours
- **Practitioner Executive Committee** - One round of review

Please note the following:

- Study PIs/teams may have already had design input from network staff, such as a Node Director. In these instances, previous consultation time will be counted toward the available time allowed as a means of providing equal access to network resources.
- The Menu of National Dental PBRN Resources is provided to Study PIs/teams for informational purposes only and is not meant to be submitted to the network.

2) Contact the NIDCR Program Director for Practice-Based Research for current guidance for accessing network resources

Click the link to the NIDCR Program Director and send an email if you would like to discuss the process for accessing network resources.

3) Submit an email to the network mailbox and NIDCR Program Director for Practice-Based Research with attached specific aims and study design overview

The email text can be short and will not be part of the initial review of the attached documents.

- Prepare two separate documents:
- Specific aims page (maximum 1 page)
- Study design and procedure overview (maximum 1 page)

Send the two documents via email to:

- CHR-nationalDentalPBRN.Resources@kpchr.org;
- & NIDCR dena.fischer@nih.gov

Initial review process and confidentiality of the submitted information

The specific aims and study design and procedures overview will be initially screened by a network coordinating center staff person. The documents will then be forwarded to the network PIs and NIDCR Program Director for Practice-Based Research for review. In some cases, Study PIs may be asked for additional details before review.

Please note that these requests are handled according to level of development and the order in which they are received. While all efforts are made to ensure those eligible for network resources are connected to requested resources in a timely manner, submissions should be received within 6-8 weeks of a FOA due date in order to allow for adequate processing time and resource assignment and access. Resource availability is also dependent on the capacity of network resources.

All information submitted to network PIs, the NIDCR Program Director for Practice-Based Research, and other staff involved in the review process is considered confidential.

Information for developing proposal budgets and budget justifications

As you prepare your application, you will need to consider which items to include in your budget. Items to include for the National Dental PBRN Administrative & Resource Center (ARC) and the Network Coordinating Center (NCC) comprise those listed in the Excel file entitled "[Description of National Dental PBRN Resources for Grant Applicants](#)" available on the NIDCR instruction page for Researchers Proposing a Study Idea.

To ensure equitable treatment of all potential applicants, the ARC and NCC cannot provide a budget or assist with writing your budget justification narrative. In your application there is no need to have a subaward from your institution to either the ARC or NCC institutions at this phase of the process.

National Dental PBRN Administrative & Resource Center (ARC)

In the Description of National Dental PBRN Resources for Grant Applications excel file, you may include salary support for a Principal Node Coordinator (row 8 in the file) and Node Coordinator(s) (row 9). Per the applicable FOA, you can budget allocations as stated in the file. Based on the project scope, Node Coordinator effort allocations may need to be modified prior to the start of the UH3 phase pending discussions between the project team, NIDCR, and the ARC. For budgeting purposes, you can use a 1.0 FTE salary of \$75,000, plus 50% fringe benefits and 60% F&A rates. Actual amounts will vary by region and personnel assigned to the study.

You also may include funding to remunerate patient-participants and practitioners for participating in or conducting the study, as stated in row 11. The dollar amounts for this remuneration will vary based on the time required of the participant or practitioner. Remuneration amounts from the network's previous studies have been mentioned in several of its [peer-reviewed publications](#) and for some studies are stated on the [National Dental PBRN results page](#).

You also may include funding to pay for travel and food/beverage costs for Node Coordinators to conduct protocol training in practices and study monitoring or closeout visits. The typical dollar amounts are specified in row 12.

Questions about the ARC component can be directed to [Gregg Gilbert](#).

Network Coordinating Center (NCC)

In the Description of National Dental PBRN Resources for Grant Applications excel file, there is text under columns C, E and F that describes the roles of the Study Manager, the NCC Data Manager and the NCC biostatistician. If you choose to include NCC staff besides the NCC Data Manager, you can use this text for creating your budget justification. In addition, the NCC can provide you with the biosketch for the biostatistician you have been working with during the study idea development phase, if you have already engaged one. It is important to note that this may not be the biostatistician you will ultimately be assigned if you are funded.

Each study is responsible for the selection, purchase, distribution, and management of the devices used to collect data. The National Dental PBRN NCC will provide recommendations on type of device if needed. You can budget between \$200-\$400 per tablet/practitioner depending on the tablet operating system and capabilities needed for the study. Studies should plan to purchase additional tablets to serve as a backups in the event an assigned tablet is lost, stolen, or otherwise broken. Studies may also consider purchasing a warranty for tablets to insure against drops, spills and malfunctions.

The study team should plan for technical assistance with the tablets to be covered through their institution's IT department. It is the study team's discretion whether or not this needs to be accounted for in the budget proposal and should be consistent with standard procedures at the institution.

The NCC is responsible for the development of all study-specific data collection systems unless a study defined application (e.g., training app) is needed. The data collection systems via the NCC-supported "Hub" and REDCap will be accessible via a URL which can be accessed via a web browser. More specifications related to data collection systems can be discussed further between the NCC and study teams as needed.

If you have any questions about the NCC, please contact Network Coordinating Center Technical Director [Reesa Laws](#) or Network Coordinating Center Director [Mary Ann McBurnie](#).

CONDUCTING THE STUDY

Your Grant Is Funded – Now What?

Congratulations! Your study has been funded! Upon receipt of a notice of grant award from NIDCR, your team will meet with network directors and the NIDCR Program Director for Practice-Based Research to begin the integration process. Study PIs and other team members will join relevant network committees and begin developing the study protocol and other study-related documents. Network staff will be assigned to the study team to help support protocol development.

Protocol/Study Development

Following are key questions to consider in creating a protocol and developing the study.

Study population, timelines and flexibility

- Will network practitioners be able to identify a sufficient number of patients?
- Can patients be easily identified by dentists and staff?
- Are timelines and recruitment targets flexible?
- Are follow-up contact procedures flexible?
- Is there scientific rationale for the selected data collection windows?
- Is sufficient time allotted for study activities (i.e., enrollment, in-person follow up, patient follow-up at home, practitioner completion of study forms)?

Practitioner and practice burden

- Is the length of the study form acceptable?
- Does the study form ask questions that directly relate to specific aims?
- Are administrative tasks easy to complete (e.g., image upload, screening log)?
- Will enrollment procedures interrupt practice flow?

Patient burden

- Is the length of the study form acceptable?
- Are study forms easy to understand and answer?

Practitioner Recruitment and Engagement

The following points are important to consider pertaining to practitioner recruitment and engagement:

- The Administrative and Resource Center includes a Practitioner Recruitment and Engagement Component resource that is equitably available to the research teams.
- The network informs practitioners of upcoming studies through a variety of methods (e.g., meetings, email announcements, monthly newsletters)
- A member database enables regional Node Coordinators to develop a targeted, regional practitioner recruitment plan, per each study protocol's inclusion and selection criteria
- Regional Node Coordinators maintain ongoing relationships with practitioners that they leverage to select, notify, and encourage practitioner study participation
- Regional Node Coordinators provide practitioners with specific information about studies, including how much time they need to commit and over what period
- Practitioners choose to participate in network studies on a study-by-study basis
- Practitioners and dental office staff who are involved in the informed consent process must have approved human subjects protection training

Protocol Training

Practitioners and dental office staff involved in patient recruitment and/or data collection are required to receive study-specific protocol training. Prior to the training, Node Coordinators provide practitioners with study forms, other relevant study materials, and a regionally tailored Practice Training Manual.

Protocol training involves:

- Attendance at a remote or in-person protocol training session provided by a regional Node Coordinator
- Review of the Practice Training Manual (see box below)
- Discussion of implementation strategies for the clinic
- Review of key elements of human subjects protection and HIPAA compliance

Patient Screening, Recruitment, and Consent

Screening for eligibility should include the following considerations:

- When developing inclusion and exclusion criteria, consider fewer exclusion and more inclusion criteria in order to capture a greater number of eligible patients.
- Plan for quick screening and options for self-screening.

Recruitment takes place during patient visits; thus, there is limited time to present an overview of the study and to consent participants. As a result:

- The study description must be concise.
- There must be an incentive to participate.

Consent begins by informing patients of the study purpose, proposed procedures, patient rights, and risks or benefits, followed by actual patient approval. Participants must be willing *and* informed. It is important to note that:

- Verbal consent speeds up the process and reduces the documentation burden on both practitioners and participants.

PRACTICE TRAINING MANUAL

Practice training manuals are user-friendly guides for practitioners and practices that contain information on study procedures using flow charts and figures. These manuals include region-specific information including IRB requirements and administrative Node contact information. Sections of the training manual may be formatted as laminated “at-a-glance” references suitable for the dental operatory.

Each clinical study with patient enrollment has a unique practice training manual, with procedures specific to the study, as a reference for practitioners and their office staff and to facilitate consistency in protocol implementation and data collection across patients and practitioner offices.

Practice training manuals detail required procedures to:

- Adhere to the protocol
- Protect the rights and safety of participants
- Collect complete information on all enrolled participants
- Establish quality-management measures to maintain high standards for data quality
- Provide strategies for completing study procedures during regular patient flow
- Ensure timely enrollment without unnecessary office schedule disruption
- Store documents securely and so they are easily retrievable
- Record and report adverse events to PBRN personnel

Data Collection

Data are usually collected from practitioners and office staff during patients' normally scheduled appointments and reviewed for continuity and completeness by study staff. Regional Node Coordinators communicate by email or telephone with practitioners if questions arise about the data or information needs to be shared. Additionally, data may be collected from patients independent of in-office visits.

Data are collected from patients and/or practitioners using web-enabled electronic devices (tablets, smart phones, computers). Patient-facing data and supporting documents are usually in English and Spanish. In addition to clinical report forms, previous network studies have collected information using odontograms, digital radiographs and photographs, and electronic downloads.

Always keep in mind that *practitioners are not seasoned researchers and need easy-to-use tools to perform research-related activities!* Consider these options in collecting data:

- Electronic data collection (ideal format)
- Short study forms
- Recommended for patients - links to forms via email/text if there is a between-visit follow-up
- Recommended for practitioners - capture data in real time as well as after visits because of the potential for unforeseen practice disruptions

Network Publications and Presentations of Study Results

Dissemination of study results is a crucial function of research done with the Dental PBRN.

Practitioner involvement in publications and presentations is an important feature of the network's team approach to science: Practitioners who were involved in studies are encouraged to be part of the writing teams for peer-reviewed manuscripts and conference presentations. Typically, the lead author of a manuscript or presentation abstract will work with regional node directors to identify one practitioner from each region to provide input on study conduct and clinical perspective.

Resources

Following are key links to information that will support your exploration of the network and engagement with dental practice-based research:

National Dental PBRN webpages

- Network homepage: www.NationalDentalPBRN.org
- Network publications and presentations: bit.ly/2WWnivU
- National Dental PBRN YouTube channel: www.youtube.com and search “National Dental PBRN”
The Network maintains a YouTube channel for posting presentations from practitioner meetings and scientific symposia.
- Network studies: bit.ly/3aBZZLQ
- Network study results: bit.ly/3bKwZSk
- Network training: bit.ly/2X1j1HF
- Network Orientation training video: bit.ly/2Jxrs5C
- Network continuing education: bit.ly/3bUtxon

National Institute of Dental and Craniofacial Research (NIDCR) webpages

- Propose a study idea and related resources: bit.ly/2R4i79j

STAY CONNECTED WITH THE NATIONAL DENTAL PBRN



[National Dental PBRN main page](http://www.NationalDentalPBRN.org)



[National Dental PBRN Twitter account](#)



[National Dental PBRN Youtube channel](#)



[National Dental PBRN Facebook page](#)



[National Dental PBRN LinkedIn page](#)