ORIENTATION HANDBOOK FOR

THE NATIONAL DENTAL PRACTICE-BASED RESEARCH NETWORK

(NATIONAL DENTAL PBRN)

A network about, with, and for practitioners and their patients

The nation's network

***Practical science* done for the immediate benefit of real-world clinical practice.**

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

A BRIEF HISTORY OF THE NATIONAL DENTAL PBRN

The National Dental Practice-Based Research Network (National Dental PBRN) began in April 2012 with a grant funded by the National Institute of Dental and Craniofacial Research (NIDCR), one of the Institutes of the National Institutes of Health (NIH). The NIDCR press release for this grant is publicly available at http://www.nih.gov/news/health/apr2012/nidcr-12.htm. The award period is April 6, 2012 to March 31, 2019. The grant number is U19-DE-22516.

In 2005, NIDCR funded three regional networks for the period 2005-2012. These three networks were "The Dental PBRN" (DPBRN), Northwest PRECEDENT, and the PEARL network. The DPBRN was administratively based at the University of Alabama at Birmingham (UAB) and comprised four U.S. regions and one Scandinavian region. The PRECEDENT network was administratively based at the University of Washington and Oregon Health & Science University, and comprised practitioners from several states in the western and northwestern U.S. The PEARL network was administratively based at New York University and predominantly comprised practitioners from the Northeast U.S. Many lessons were learned during this seven-year period, most of which are described in more detail in the article: *Lessons learned during the conduct of clinical studies in The Dental PBRN. Journal of Dental Education 2011; 75(4): 453-465.*

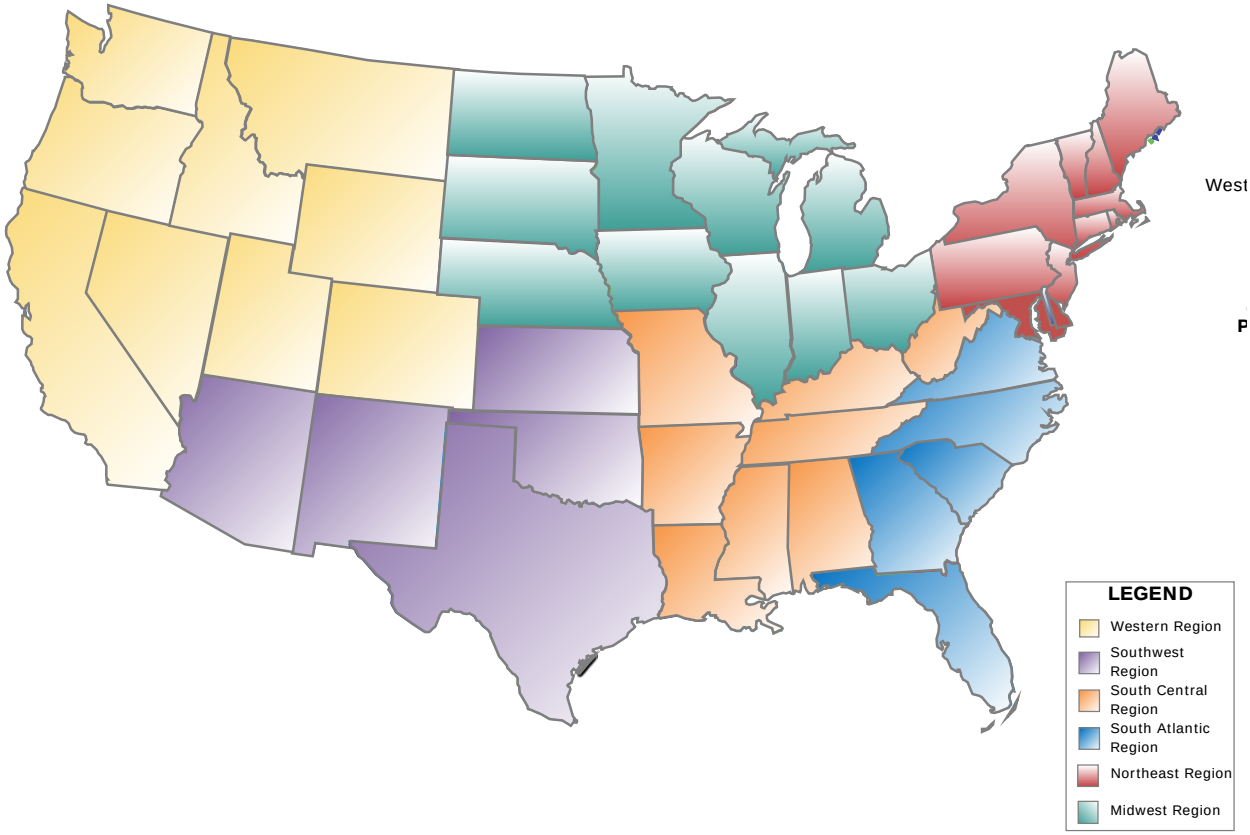
With its release of a funding opportunity announcement in 2011, NIDCR declared that it would fund the next phase of evolution of its PBRN initiative in 2012 as a single, nationwide network, and would no longer support regional networks.

NETWORK ADMINISTRATIVE STRUCTURE

The mission of the nation's network is "To improve oral health by conducting dental practice-based research and by serving dental professionals through education and collegiality". It is committed to maximizing the practicality of conducting research in daily clinical practice across geographically dispersed regions, so its structure is designed to focus some activities at the regional level (e.g., close interactions with practitioners), and other activities that can be done on behalf of the entire network centrally (e.g., study development).

The network comprises six regions of the United States. Practitioners in all of the U.S. states and territories are eligible for enrollment. Training for some studies may be provided via webinar or telephone conference call and therefore may be open to broad geographic areas. Other studies will require in-office training, and enrolled practices may be clustered within driving distance near the regional administrative bases. The locations of the regional administrative bases for these regions are shown below. The network's central administrative base is at UAB. The network's Coordinating Center is at Westat in Rockville, MD. Contact information for each of these sites is provided in a different document. Each region and the Coordinating Center has its own budget contracted with the National Network Director.

The National Dental PBRN Regions



Western Region (region #1)
Administratively based at the Center for Health Research, Portland, OR.
This region comprises Alaska, American Samoa, California, Colorado, Guam, Hawaii, Idaho, Montana, Nevada, Northern Mariana Islands, Oregon, Utah, Washington, Wyoming.

Midwest Region (region #2)
Administratively based at the HealthPartners Institute for Education and Research in Minneapolis, MN.
This region comprises Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin.

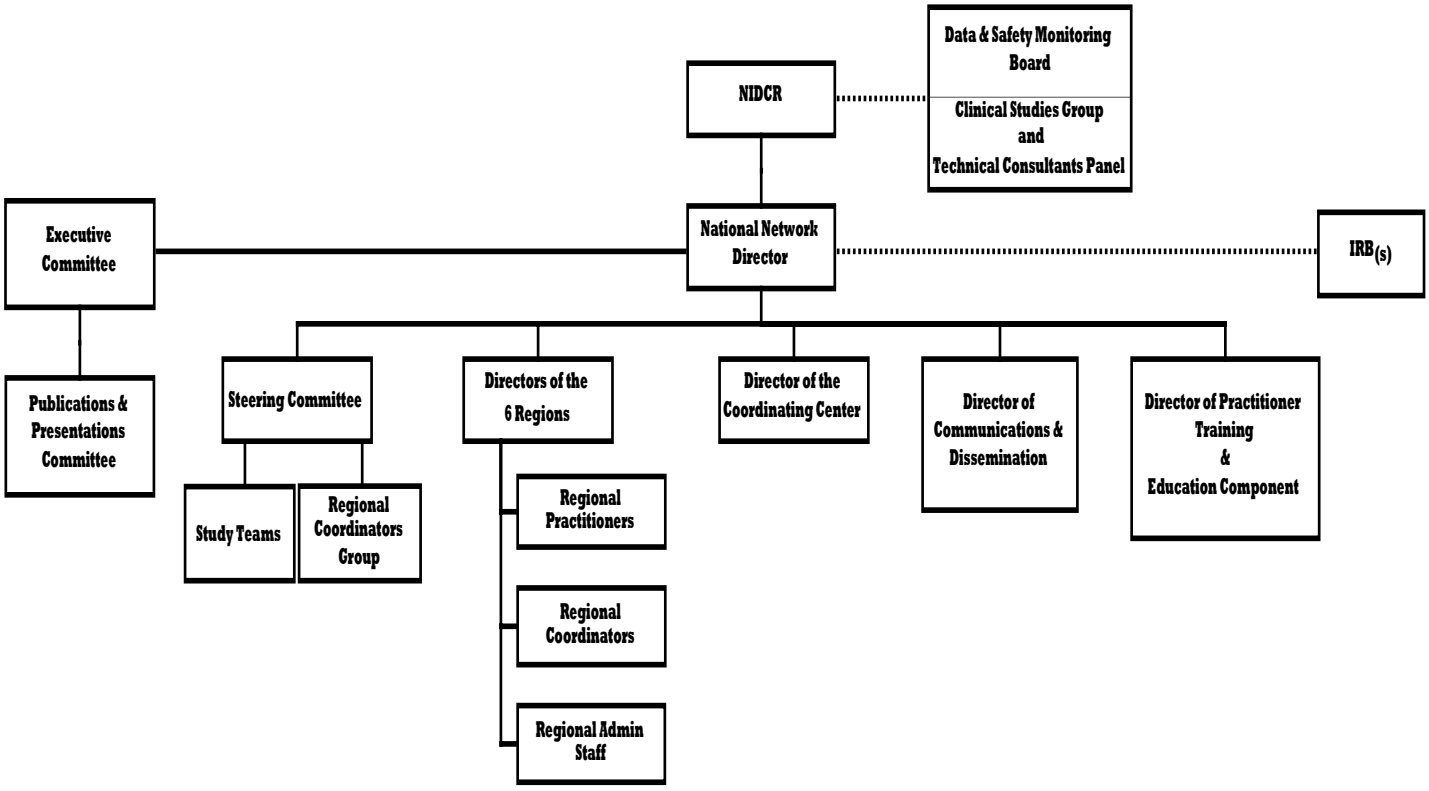
Southwest Region (region #3)
Administratively based at the University of Texas Health Science Center at San Antonio in San Antonio, TX.
This region comprises Arizona, Kansas, New Mexico, Oklahoma, Texas.

South Central Region (region #4)
Administratively based at the University of Alabama at Birmingham in Birmingham, AL.
This region comprises Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Tennessee, West Virginia.

South Atlantic Region (region #5)
Administratively based at the University of Florida in Gainesville, FL.
This region comprises Florida, Georgia, North Carolina, South Carolina, Virginia.

Northeast Region (region #6)
Administratively based at the University of Rochester in Rochester, NY.
This region comprises Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, US Virgin Islands, Vermont.

The Coordinating Center for the national network is administratively based at Westat in Rockville, MD.



The network's organizational chart is shown above.

NIDCR (www.NIDCR.NIH.gov) is the main funder of the network. It is the federal government's lead agency for scientific research on oral, dental, and craniofacial health and disease. NIDCR is one of the National Institutes of Health in the U.S. Department of Health & Human Services, and is the main funder of oral health research in the nation. The Institute has been the NIH leader in its commitment to PBRN research, thus providing an unprecedented opportunity for the dental profession to improve the nation's oral health. Drs. Donald DeNucci and Dena Fischer are the NIDCR Program Officials for the national PBRN initiative.

National Network Director (NND). The NND is responsible for overall scientific and administrative leadership, operations and fiscal management, and chairing the Executive Committee, among other duties. The NND is Dr. Gregg Gilbert at UAB.

Coordinating Center (CC). The Coordinating Center provides expertise in study design and statistical support, develops and maintains databases and information systems, conducts data analyses, participates in publications, among other duties. It is composed of faculty biostatisticians and staff with expertise in data management and analysis, study design, informatics, and communications technology. The Director of the CC is Dr. James Korelitz at Westat. The CC coordinates more than just data, so a DCC appellation would not be the preferred term so as to maintain continuity with terminology used in the 2005-2012 cycle.

National Director of Communications & Dissemination. This director oversees the network's communication and dissemination policies and activities, and directs the network's web site, its quarterly newsletter, a monthly e-update, and a member-only electronic mail list server. The Director of Communications & Dissemination is Dr. Sonia Makhija at UAB.

National Director of Practitioner Training & Education Component (PTEC). This director oversees the network's practitioner training and education activities. The Director of PTEC is Dr. Valeria Gordan at the University of Florida.

Executive Committee (EC). The EC is the key decision-making body of the network. It is composed of six practitioners representing each of the six Nodes, the National Network Director, and the Coordinating Center Director. NIDCR Program Official(s) serve in an ex officio non-voting advisory capacity. The main role of this committee is to prioritize research topics for protocol development and to review protocols prior to submission. The NND serves as the Chair of the EC. The EC meets on a monthly to quarterly basis, depending on the volume of anticipated work. The EC evaluates study ideas, study design, practitioner remuneration, network operations, among other duties.

Steering Committee (SC). The SC decides how best to implement the decisions of the EC; assists investigator groups with developing study applications into a more-final form before they are sent to the Executive Committee; and seeks to maximize coordination of tasks across regions, in conjunction with the Regional Coordination Group. Its voting members are the NND, Director of the CC, the Director of each of the six Regions. The Deputy Directors of each Region and a representative from the Regional Coordination Group also attend. The committee meets monthly by telephone conference and annually face-to-face. The NND serves as the Chair of the SC.

Regional Coordination (RC). The RC group comprises the Regional Coordinators from each region, a representative from the NND office, and a representative from the CC. It meets monthly by telephone conference and annually face-to-face to discuss regional coordination and implementation issues and makes recommendations to the SC regarding improving network operations. The Chair position of this committee rotates among the network's regions on an annual basis effective January 1st of each calendar year.

Study Teams. Once a study concept has been approved, a Study Team is formed. This team administers the study from protocol development, to feasibility and pilot testing, to data collection, to data analysis, to study closure. The team includes subject experts and is study-specific. The team is constituted by the NND in concert with the proposed Study Principal Investigator (SPI) and the NIDCR CSG. While forming the Study Team, the network may solicit expertise nationally/internationally if advisable, or only use expertise already available in the network, depending on what the study topic and study design may require. The composition of the team varies with the stage of the study. The study is typically administered via monthly conference calls of the team, whose only agenda items have to do with that study. During the protocol development phase, the minimum composition is the SPI, the subject expert(s), the NND, a Regional Coordinator, and a practitioner. At a later stage, representatives from each region join the monthly Study Team conference calls during the data forms development, feasibility testing, pilot testing, and data collection phases. After data collection for the study has ended and its data set(s) are locked, the Study Team typically dissolves and at that point the SPI takes responsibility for leading data analyses and manuscript preparations, a process which itself may involve conference calls of personnel involved in manuscript preparation from the study.

NIDCR Clinical Studies Group (CSG). The CSG formalizes the process for Institute evaluation and approval of network projects. It is composed of NIDCR Program Officials, OCTOM (Office of Clinical Trials Operations & Management), and others from the Institute. Once a study concept has been approved by the Executive Committee, it is sent for review by the CSG. The CSG comprises experts in study methodology, scientific content, patient safety, and program knowledge. The CSG can approve with or without recommendations, or disapprove the concept. If disapproved by the CSG, no further study development occurs. If the concept is approved by the CSG and a Complete Protocol is developed and approved by the EC, the CSG evaluates the Complete Protocol and provides feedback as needed during an iterative process with an eye toward eventual approval of the final Complete Protocol.

NIDCR Technical Consultants Panel. This is a panel of study-specific subject experts recommended by NIDCR and chosen by the NND to guide specific aspects of protocol development.

NIDCR Data & Safety Monitoring Board (DSMB). The DSMB is an independent group of experts that advises NIDCR and study investigators on clinical studies, especially those that involve an intervention. The responsibilities of the DSMB include: (1) monitoring human subject safety by reviewing and evaluating the accumulated study data, and, when appropriate, efficacy or effectiveness; (2) review study conduct and progress; and (3) make recommendations to NIDCR concerning the continuation, modification, or termination of the study. Study-specific data as well as relevant background information about the disease, patient population, procedures and progress of the study are considered.

Publications & Presentations Committee (P&P). The network has a Publications and Presentations Policy, which is available at the network's public web site. One component of this policy is the P&P Committee. The purpose of this committee is to implement the publications and presentations policy, to ensure compliance with it, and to review and approve all of the network's manuscripts,

publications, abstracts, and study-related presentations. The committee comprises a practitioner, representatives from two network regions, and representatives from the Office of the NND and CC. This committee encourages network publications and presentations, manages the publications process, and ensures compliance with the policy. The Chair of the P&P is Dr. Brad Rindal at the HealthPartners Institute for Education and Research. All network investigators and staff are required to abide by the network's "Data Analysis, Publications, and Presentations Policies" document. The current version of this policy is kept at the network's public web site at http://nationaldentalpbrn.org/publication.php.

Practitioner Compensation System (PCS): The PCS provides timely and accurate compensation to practitioners and patients engaged in network projects. It is an efficient system that is linked to predetermined deliverables. The system includes an adjudication functionality to address disputes associated with compensation claims.

The National Dental PBRN EXECUTIVE COMMITTEE

The Executive Committee (EC) is a key decision-making body for the nation's network. Its members comprise one practitioner from each of the six regions of the network, the National Network Director, the Director of the network's Coordinating Center, and the NIDCR program officials (in an *ex officio*, non-voting role). Practitioner members serve for three-year terms. Practitioners constitute the majority voting authority on the Executive Committee.

The duties of the EC are to make certain decisions and policy regarding studies done in the network and matters that directly affect the network's practitioners. It makes decisions about changes in study procedures as necessary; reviews and implements recommendations from the Institutional Review Board and/or Data and Safety Monitoring Board; reviews progress of studies in achieving their goals; and reviews data collection procedures. The EC also prioritizes research topics for study development, and reviews studies prior to further development at successive stages. The EC usually meets every month. The typical meeting is held by teleconference, but once each year it meets face-to-face.

The EC agenda and supporting documents are sent as an Adobe "pdf" (portable document format) file by email in advance of the EC meetings. This usually occurs one week before the meeting. This packet also has the call-in number.

In addition to formal meetings, it is not uncommon for EC members to have "virtual" discussions of topics by email in between EC meetings. For some topics that do not require much discussion, formal votes are also handled by email.

These are the eligibility criteria for nomination as a practitioner representative on the EC:

1) must be a licensed practitioner engaged in the regular practice of dentistry or dental hygiene;
2) must be a general dentist or a dental hygienist who sees patients in a general practice setting;
3) must have participated in at least one network clinical study (i.e., the network Enrollment Questionnaire is not sufficient);
4) must have access to e-mail, be able to receive attachments via e-mail, and be willing to communicate via e-mail on a regular basis;
5) must be able to participate in the regularly-scheduled Executive Committee meetings that are held by teleconference and during face-to-face meetings at locations throughout the U.S.

The current members of the EC are listed at the network's public web site.

The EC makes decisions by majority vote. For an EC meeting in which any votes are taken, a simple majority of the EC membership must be in attendance, although at least three of practitioners must be present. This does not preclude the EC from having a discussion during a meeting that does not have such a quorum, but no vote can be taken.

THE STUDY DEVELOPMENT PROCESS

A key operating principle for the nation's network is that all studies answer questions that can improve the daily clinical practice of dentistry. Furthermore, the research itself is done within the practices of the network members. This situation creates a healthy tension between the needs of a sound research project and the need to minimize disruption of daily clinical practice. In this sense, the process cannot require the researchers to become practitioners, nor the practitioners to become full-time researchers. The overall process of study development appears in a later section (National Dental PBRN Protocol Development Process Timeline). Importantly, practitioners provide input at each step of the process. This is especially true of the practitioners on the Executive Committee. It is imperative to the success of the nation's network that it conducts studies that practitioners find useful, interesting, feasible, and that have the potential to provide results to improve daily clinical practice. Ideas for studies are obtained from responses provided on the enrollment questionnaire, in face-to-face meetings (e.g., at orientation sessions delivered in continuing education format, at annual meetings of practitioners, or in visits to the practice), from the academic community, or at the network's public web site. Ideas for studies are discussed and prioritized by the Executive Committee. Some study ideas are rejected by the Executive Committee, typically because they are judged not to be of broad interest to practitioners, judged not to be sufficiently impactful on routine clinical practice, or because they are not feasible to conduct in daily clinical practice.

Study Concept Phase

The first step is for the proposed Study Principal Investigator (SPI) is to complete the Study Concept Template, which is shown on pages 12-14. A Microsoft Word version of this template is also available on the network's public web site. We recommend that persons interested in submitting a study concept contact the applicable Regional Director. The Regional Director can help ensure applicability of the research idea to the PBRN context and help guide the idea through the development process. Once the research idea is developed and formatted into the Study Concept Template and has undergone review by the Regional Director, it is sent to the NND for review. Once approved by the NND, the completed Study Concept becomes an agenda item for a meeting of the Executive Committee. It is helpful if the researcher proposing the Study Concept, who is referred to as the Study Principal Investigator (SPI), can attend this meeting (via telephone) to discuss the Study Concept and to answer any questions that the committee has. If the Executive Committee approves the Study Concept, the NND will forward it to the NIDCR Clinical Studies Group (CSG) for additional consideration. The NIDCR CSG will provide its decision using a Study Concept Evaluation Card, oftentimes providing additional feedback during an interactive, iterative process that may involve conference call(s) between NIDCR, the SPI, and the NND. If the NIDCR CSG approves the concept, a Westat Study Manager is assigned to the study, and then a Study Team is proposed.

Study Team Phase

The Westat Study Manager will be introduced to the SPI and is an individual who is knowledgeable about the development and implementation of network studies. The Study Manager will provide the SPI a Study Team Composition Template and a Work Instructions document when the SPI gets to this point in the process.

The Study Team and Study Timeline are proposed to the NIDCR CSG by the SPI and the NND. Biographical sketches (using the PHS Biographical Sketch Format page at http://grants.nih.gov/grants/funding/phs398/phs398.html) of primary study team members, and short biographical narratives of other team members, are submitted by the NND to the NIDCR CSG for approval. A Study Timeline should also be proposed, which includes the key tasks planned for both the Study Development Phase and the Study Implementation Phase. The Westat Study Manager will propose to the SPI a first draft of this timeline.

A Study Team comprises the SPI and other scientific and content expert(s) that the SPI, NND, and NIDCR CSG judge to be appropriate. Typically the Study Team would also include at least one practitioner, a Coordinating Center biostatistician, a Westat Study Manager, and a Lead Regional Coordinator are assigned to the Study Team. The SPI should carefully consider each proposed Study Team member; each individual should offer specific expertise that has the potential to improve the study. While forming the Study Team, the network feels free to call on expertise nationally/internationally if warranted, or may use expertise already available in the network, depending on what the study topic and study design may require. The job descriptions of the Westat Study Manager, the Lead RC, and the network Program Coordinator appear on pages 15-19.

The network must adhere to consistency of Study Teams and supported effort across network studies. SPIs should carefully consider each proposed member of the Study Team and what expertise each member would bring to the team, while simultaneously taking into account the goals and deliverables of the Study Development Phase, and later, the Study Implementation Phase. Each Study Team member should offer specific expertise that has the potential to improve the study. Some expertise may best function in the role of consultants instead of investigators. Study Team resources available through the network infrastructure funding, such as a Coordinating Center biostatistician, a Westat Study Manager, and a Lead Regional Coordinator, are assigned to each Study Team by the National Network Director and are already available as part of the Study Team. The additional expertise proposed for the Study Team should not overlap with this expertise.

Study Development Phase

These key steps occur during the Study Development Phase: (1) Complete Protocol development; (2) Case Report Form (CRF) development; (3) input from Regional Administrative Sites; (4) review and approval of the Complete Protocol by the Executive Committee and the NIDCR CSG; (4) review and approval of the Complete Protocol and CRFs by the DSMB, if a DSMB review is required for the study; (5) IRB application(s) is ready for submission. Although not finalized until the Study Implementation Phase, development should begin on these documents during the Study Development Phase: (a) Manual of Procedures; (b) Clinical Monitoring Plan; (c) Data Management Plan; (d) Clinical Quality Management Plan; and (e) Practice Training Manual.

Once the Study Team and Study Timeline are approved by the NIDCR CSG, the Westat Study Manager contributes to development of study-related documents and assists with all aspects of study development and central coordination from that point forward. During the Study Development Phase, the Westat Study Manager works with the Study Team to develop the approved study concept into a Complete Protocol using the applicable NIDCR protocol template. This begins the Study Development Phase of the research project. For observational studies, the NIDCR observational protocol template is utilized, and for intervention studies, the NIDCR interventional protocol template is used. These protocol templates are located at http://www.nidcr.nih.gov/Research/toolkit/. Scroll down to the section "Protocol Templates" to find the appropriate protocol template as a Microsoft Word document. Version control of all documents is important, so investigators are directed to follow the guidelines at http://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/VersionControlGuidelines.htm.

The Westat Study Manager works with the Study Team to develop Case Report Forms (CRFs; data collection documents) and is also responsible for development of other study-related operations documents (described below), some of which may be developed simultaneously with the Complete Protocol and CRFs. The Westat Study Manager serves in the capacity of "owner" of the Complete Protocol, CRFs, and other study-related documents and is responsible for version control of these study materials.

Typically, preliminary versions of the Complete Protocol are reviewed by the Executive Committee to maximize the study's applicability to and impact on daily clinical practice, feasibility, and scientific merit. After the Complete Protocol is approved by the Executive Committee, the NND forwards it to the NIDCR CSG for its review and approval, oftentimes during an interactive, iterative process that may involve conference call(s) between NIDCR, the SPI, and the NND. A DSMB may be advisable for certain studies, and if so, the Complete Protocol, informed consent documents, and other study-related documents may be reviewed by the DSMB. If approved by the DSMB, the Complete Protocol, informed consent documents and Case Report Forms are then submitted to the Institutional Board from each network region for review of human subjects considerations.

Study Team investigators may request salary support for a specified period of time in order to develop a comprehensive Complete Protocol and CRFs. This "Study Development Phase" is funded via a Study Development Contract, established between the Study PI's institution and UAB. The Westat Study Manager will provide the SPI a Study Development Phase set of Work Instructions when the SPI gets to this point in the process. If a request to fund the study development period is anticipated, then this request should accompany the Study Team and Study Timeline documents when these documents are submitted to the NND for approval. The length of this support will be decided upon specific to each study; the proposed Study Team should propose a specific number of months and percentage time of support and justify that length of time. The typical expectation would be 6-10 months of support, depending on whether the proposed study involves clinical data collection or is limited to a practitioner questionnaire study, and whether a DSMB review is required. A request to fund the Study Development Phase should be accompanied by budget documents. These budget documents should be submitted for review and approval: PHS 398 Form Pages 1 and 4; Checklist Form Page; Continuation Format Page for providing the Budget Justification narrative; Other Support Format Page. These forms are available at http://grants.nih.gov/grants/funding/phs398/phs398.html. Funding for the study development phase ends when the Complete Protocol and CRFs are developed to the point where the EC and NIDCR CSG have approved the Complete Protocol and an IRB

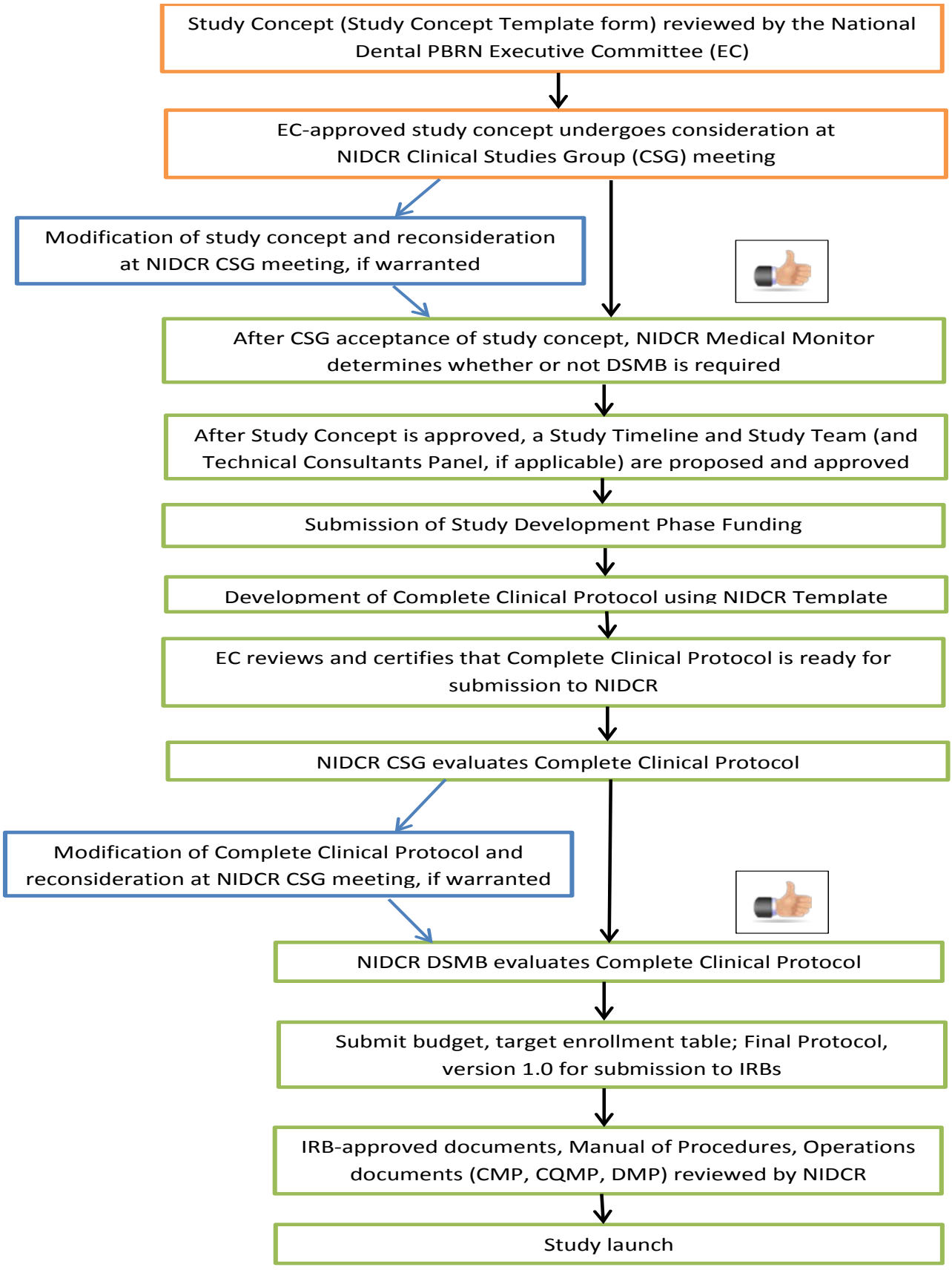
application is ready for submission. The Complete Protocol, CRFs, and IRB application are the key deliverables for the Study Development Phase. Study Development Phase funding is provided to meet these deliverables, and is not extended because the agreed-upon timeline is not met.

Study Implementation Phase

These key steps occur during the Study Implementation Phase: (1) while IRB applications are under review, these documents can be finalized pending any changes due to IRB review: (a) Manual of Procedures; (b) Clinical Monitoring Plan; (c) Data Management Plan; (d) Clinical Quality Management Plan; (e) Practice Training Manual, (f) Enrollment Log, if applicable; (2) pilot and/or feasibility testing of CRFs and study procedures on a small number of network practices, if needed; (3) enrollment and training of practitioners; (4) data collection; (5) data analysis; (6) report and manuscript preparation.

The Westat Study Manager will provide the SPI a Study Implementation Phase set of Work Instructions when the SPI gets to this point in the process. The Study Timeline should be updated at this time, having now already completed the Study Development Phase, and now having updated information available about the Study Implementation Phase timeline. Study Implementation Phase budget documents and a targeted/planned enrollment table for the full study should be submitted to the NND for review and approval (PHS 398 Form Pages 1, 4 and 5; Checklist Form Page; Continuation Format Page for providing the Budget Justification narrative; Other Support Format Page; Targeted/Planned Enrollment Table; available at http://grants.nih.gov/grants/funding/phs398/phs398.html). Additionally, an itemized budget of payments to practitioners and/or patients that will be needed for the study should be provided, although this budget should be separate because these payments are made by UAB and Westat, and therefore are line items in their budgets.

Study procedures using approved versions of CRFs and other study-specific materials are pilot tested with selected practitioners across the network. Pilot testing may lead to changes in study procedures, CRFs and/or other study materials to optimize use in a diverse range of practice settings. Once the study procedures and CRFs have been finalized, a study is implemented across the network.


Study Concept (Study Concept Template form) reviewed by the National Dental PBRN Executive Committee (EC)
EC-approved study concept undergoes consideration at NIDCR Clinical Studies Group (CSG) meeting
Modification of study concept and reconsideration at NIDCR CSG meeting, if warranted
After CSG acceptance of study concept, NIDCR Medical Monitor determines whether or not DSMB is required
After Study Concept is approved, a Study Timeline and Study Team (and Technical Consultants Panel, if applicable) are proposed and approved
Submission of Study Development Phase Funding
Development of Complete Clinical Protocol using NIDCR Template
EC reviews and certifies that Complete Clinical Protocol is ready for submission to NIDCR
NIDCR CSG evaluates Complete Clinical Protocol
Modification of Complete Clinical Protocol and reconsideration at NIDCR CSG meeting, if warranted
NIDCR DSMB evaluates Complete Clinical Protocol
Submit budget, target enrollment table; Final Protocol, version 1.0 for submission to IRBs
IRB-approved documents, Manual of Procedures, Operations documents (CMP, CQMP, DMP) reviewed by NIDCR
Study launch

National Dental PBRN Study Concept Template

(use Calibri 11-point font and do not exceed eight pages, including study schematic)

Protocol Title: <Insert protocol title>

Study Principal Investigator/Study Team
<Insert name of Study Principal Investigator. Insert names of Study Team members/investigators to date; may include "to be named [TBN]" expertise if warranted.>

Network Node/Institution <Insert Study PI's network node and institution/affiliation.>

Draft or version number and Date <Study PI controls version number/date. Use 0.1, 0.2, 0.3, etc for drafts of the study concept.>

Background and Scientific Rationale
<Describe the research/health problem that the study will address.>
<Briefly discuss any literature/prior studies that may provide background and justification for this study. Summarize experience and/or history relevant to the research>
<Provide compelling scientific rationale for the research.>

Potential Risks/Benefits
<Describe risks and benefits to subjects (practitioners and patients) and/or society.>

Specific Aims and Hypotheses
<List specific aims of the study. List the study hypothesis(es).>

Outcome Measures
<Specify primary and/or secondary outcome measurement(s) or observation(s) used to assess the effect of an intervention or, for an observational study, to describe the patterns of disease, traits or associations with exposures or risk factors which are the focus of the study. If appropriate to study design, you may wish to include independent and dependent study variables.>

Eligibility
<Identify the practitioner/patient population being evaluated in the study.>
<List inclusion and exclusion criteria for subjects (practitioners and patients).>
<Describe specifically and state the justification for any included vulnerable population or any excluded populations, for example: minors.>

Subject Enrollment and Retention
<Describe participant identification and screening.>
<Describe the primary strategy for participant recruitment and enrollment.>
<Describe the primary strategy for participant retention, if applicable.>

Study Design and Procedures

- **Study Model**
  <Describe the study design and study groups or cohorts.>
  <Describe the participant (practitioner and patient) target enrollment- per site and study total. List which National Dental PBRN region(s) would be involved. Include a brief statement indicating the sampling strategy (e.g. convenience sampling) or method used to determine the appropriate sample size for the study.>

- **Time Perspective**
  <What is the temporal relationship between the observation period and time of participant enrollment? Is the study prospective, retrospective, cross-sectional?>

- **Study Schedule**
  <Provide a description of the study schedule and timeline, including approximate number of study visits and time points of study visits.>

  Planned Accrual Period: <Insert time (months, years, etc.)>

  Planned Study Duration: <Insert time from first participant-first visit to last participant-last visit (months, years, etc.)>

  Duration of Subject Participation: <How many study visits are required for each participant? What is the expected duration of subject participation?>

- **Intervention**
  <Describe intervention if there is an intervention>

- **Data Collected**
  <Specify types of data that will be collected, e.g., photographic or radiographic images, clinical data, periodontal measurements, questionnaire responses, etc. For survey studies, describe the development or selection of the questionnaire.>

- **Biospecimens Collected**
  <List any biospecimen types to be collected and purpose for each sample type. Will biospecimens be retained for future research? If so, is DNA extraction and analysis possible from retained specimens?>

Justification for why the National Dental PBRN is the best setting for the study as compared to an academic health center or similar setting

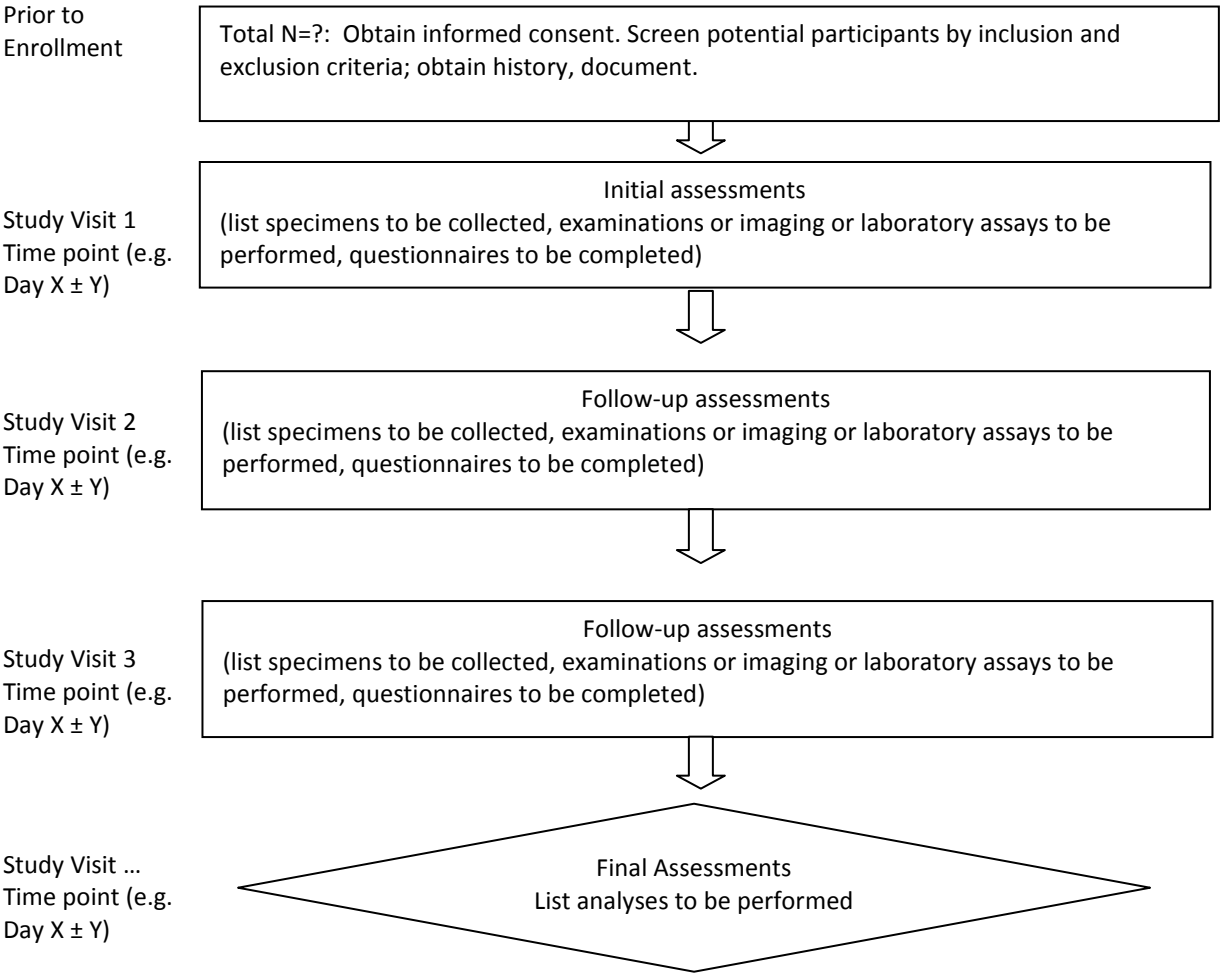
Feasibility to conduct high quality study and recruitment potential

Potential to change clinical practice

Impact on the oral health of the public

Schematic of Study Design:

{The diagram below shows the preferred format and the level of detail needed to convey an overview of a study design for an observational study. Complete each text box with study-specific information and adapt the diagram to illustrate your study design. If describing an interventional study, please use the study schematic in the NIDCR Clinical Trial (interventional) Protocol Template}



National Dental PBRN Study Manager Position Description

The purpose of this document is to describe the roles and responsibilities of a National Dental PBRN Study Manager. One Study Manager at Westat will be assigned for each National Dental PBRN study. Once the Study Team has been approved, a Coordinating Center Study Manager will be assigned to the study and will contribute to development of the Complete Protocol and other study-related documents, assisting with all aspects of study development from that point forward. Additional roles and responsibilities may be identified based on the needs of a specific protocol, but the list of tasks below provides a general overview of the expected tasks.

Protocol and Manual of Procedures (MOP)

- Assist the Study Principal Investigator (SPI) with the development of the study protocol document and serve as the "keeper" of the protocol document and related documents and be responsible for version control of these documents. Compile comments from external reviewers (Regional Directors, Regional Deputy Directors, Regional Coordinators, Study Investigators, subject area experts, etc.) and Westat protocol reviewers into one document. Maintain and distribute the updated official versions of the protocol as it is developed and finalized. Ensure compliance with the NIDCR toolkit's observational or interventional protocol template, as appropriate. Also review the protocol in general and provide any comments or suggested changes.
- Develop and maintain the study-specific MOP per the NIDCR MOP template. Request contributions to the MOP by other network staff (e.g., Regional Directors and Coordinators). Distribute the MOP for network staff and NIDCR review.
- Ensure the current version of the protocol, MOP, and any protocol-related documents are posted to the Internal Website.

Other Study Operations Documents

- In coordination with NIDCR, develop and maintain the study-specific Clinical Monitoring Plan (CMP), Data Management Plan (DMP), and Clinical Quality Management Plan (CQMP), as warranted, per the NIDCR CMP, DMP, and CQMP templates. Request contributions to these study-related documents by other Westat staff; for example, Westat's Data Management team will be the lead contributors to the DMP. Distribute the CMP, DMP, and CQMP for Westat, SPI, and NIDCR review.
- Ensure the current version of the CMP, DMP, and CQMP are posted to the Internal Website.

Training

- Participate in protocol, Case Report Form (CRF), and/or Remote Data Capture (RDC) training for Regional Administrative Sites (RAS).
- Coordinate training to ensure that protocol procedures are understood by the SPI and RAS.

Communication

- Represent Westat during conference calls between the SPI and RAS. Enhance coordination between the SPI and RAS.
- Develop draft Study Team agenda, review it with the SPI, and then forward for dissemination by the network Program Coordinator at UAB.
- Maintain a repository for problems encountered during the study and maintain Frequently Asked Questions (FAQ) logs. Evaluate problems and work with the SPI and RCs to determine and document appropriate solutions. Assist with ensuring that protocol procedures are being followed consistently across RAS and practitioners.
- Serve as the main point of contact at the Coordinating Center (CC) regarding the study for the SPI, RAS, UAB, and NIDCR.
- Enhance the coordination between the SPI and RAS.
- Keep the Westat Program Director and Westat Program Manager informed of protocol issues.
- Develop and maintain study timelines and task lists.
- Participate in internal project team meetings with the Westat Program Director, Program Manager, and other Study Managers to discuss the status of active studies. Provide reports on assigned study(ies).
- Coordinate with and serve as the back-up for other Study Managers.

- Coordinate with the SPI to develop the Study Team agenda items. The UAB Network Program Coordinator will schedule and send communications for each monthly Study Team meeting, will distribute the agenda and accompanying packet for each monthly Study Team meeting, and will take minutes for each meeting.

Reports

- Develop report specifications (e.g. accrual reports, quality control reports, etc.) and submit to SAS Programmer or Clinical Data Manager (CDM), as appropriate. Participate in the report validation, review, and approval process. Distribute reports externally and request that they are posted to the Internal Website.
- Review study data reports.

IRB

- Provide central tracking of IRB submissions (initial submission, amendments, continuing reviews, close-out, etc.)
- Track IRB-related issues, such as protocol deviations, reports, and monitoring.
- Coordinate responses to IRB issues to the six RAS IRBs, Westat, and any other involved IRBs.
- Draft annual reports for IRBs.
- Consult with Westat's Regulatory Affairs department (e.g. Regulatory Affairs Associate) for guidance on any regulatory issues.

Internal Management

- Manage tasks being completed by other Westat team members
    - Examples are provided below. This is not a comprehensive list.
        - Project Administrator
            - Work with the Project Administrator to develop a plan for administering patient or practitioner payments, if required by the protocol. Oversee the Project Administrator's tasks.
        - Information Technology (IT) Staff
            - Work with IT staff to develop an online questionnaire, if required by the protocol. Test and provide feedback to IT staff on the questionnaire.
            - Provide specifications to IT staff for needed additions to the study-specific component of the Practitioner Database (and conduct user testing/validation).
        - Clinical Data Manager
            - Work with the CDM to develop CRFs, CRF completion guidelines, and databases.
                - CRF Development example: Send the information from the protocol to the CDM, answer questions, and then review a final version.
        - Training staff
            - Work with Training staff if the protocol requires remote data entry by RCs. Oversee the plan for providing general and protocol-specific training for RCs.
        - Statistical Analyses
            - Work with statisticians responsible for analysis and confirm appropriate statistical support is provided.

National Dental PBRN Study Lead Regional Coordinator

The purpose of this document is to describe the roles and responsibilities of the Lead RC role that is assigned to each study at the Study Team phase.

Background and Duties

New to the 2012-2019 funding cycle, the National Dental PBRN is fortunate to be able to fund a Study Manager for each approved study. The Study Manager, employed by Westat, works closely with the Study PI in all aspects of study development and study implementation. After engaging in a self-assessment of the study development process after the first four approved studies, the network concluded that the process was effective, but that its efficiency would be improved by creating a formal mechanism to infuse early into the process Regional Coordinator expertise and experience. This spawned the role of "Lead RC" to advise and assist the Study PI and Study Manager with the study development and study implementation processes. The Lead RC is identified from among the Regional Coordinators in the network, yet still reports to his or her respective Regional Director. The Lead RC is not a new job; it is a new role for an existing job, the RC position. This Lead RC role is a temporary assignment that ideally will rotate among the RCs across all regions ultimately.

A Lead RC is assigned to each National Dental PBRN study after the study concept is approved and when the Study Team is formed. The Lead RC serves as a source of expertise in practice-based research and is the key representative of the dental practices participating in the research. The Lead RC's contribution focuses on designing protocol procedures to be feasible and practical in the dental practice setting.

In addition to the Lead RC, the Study Manager plays a critical role in the study development and study implementation phases. The Study Manager position description can be found within the Orientation Handbook. The Study Manager will continue to fulfill the roles and responsibilities described in that document, including serving as the "owner" of the study documents. The "owner" term is operationalized in the "National Dental PBRN Document Versioning Guidelines" document.

The Lead RC will have these duties:

Study Development Phase

- Conduct a "pre-review" from an RC perspective of the protocol, protocol overview, and study management plans.
- Attend the monthly Study Team meetings.
- If the Lead RC's schedule allows, attend other meetings of the Study Team if they are necessary.
- Work with the Westat Study Manager and Study PI to determine how studies should be planned to accommodate workflow in dental practice. When needed, reach out to key practitioners regarding feasibility questions and propose solutions based on input.
- Serve as the lead RC representative to RC colleagues as a recipient of ad hoc feedback and questions. Act as the voice of the RC group in relaying feasibility and implementation questions and feedback to the Study Team. Provide continuity of communication back to the RC group by relaying how feedback was incorporated, or if not, why it was not.
- Serve as the lead RC representative for the development or editing of practitioner-facing documents, including but not limited to study recruitment materials, CRFs, and training materials before they are sent to the entire SC/RC group for review.

Study Implementation Phase

- Work in conjunction with the Westat Study Manager and Study PI to determine how implementation is or is not fitting into normal workflow. When needed, reach out to key practitioners regarding feasibility questions and propose solutions based on input.
- If modifications to the protocol, study management plans, practice training manual, or any "practitioner-facing document" need to be made, conduct a thorough review of these documents before the changes are accepted. Advise the Study Manager, who maintains the current version of all study documents.
- Communicate regularly with the Study Manager and SPI about successes and problems occurring in the dental practices as they implement the study. This will allow the Study Manager to maintain a complete list of issues and "Frequently Asked

Questions" documents. These issues will be regularly addressed during Study Team meetings and via email communications among the Study Team members in between the monthly Study Team meetings.

Reporting and Decision Making

The Study PI is the decision maker for the study, in consultation with the National Network Director when study-specific decisions have the potential to impact the network overall, such as those that might affect the network's effectiveness, efficiency, or standardization across studies. The Study Manager and Lead RC collaborate to make recommendations about study operations (procedures, documentation requirements, etc.) and to provide input for problem solving/issue resolution.

Lead RC Assignments

There are several factors that are taken into consideration when assigning Lead RCs, as listed below. Regional Directors often take the lead on relationship building with Study PIs for protocols coming out of their region, in which case assigning a Lead RC from that region may be the best choice. Lead RC assignments will be made by the National Network Director based on input from the Study PI, Regional Directors, the RC Chair, the Study Manager, and the Westat Project Manager.

Factors taken into consideration when assigning Lead RCs:

- The region from which the study originated
- Existing relationships with Study PI
- Proximity to the Study PI
- Interest in the clinical topic and complexity of the study
- RC workload/availability
- Experience of the Westat Study Manager

Review/Revisions

After the Network puts this Lead RC role into practice and gains experience, this document will be reviewed, and updates made if necessary.

National Dental PBRN Program Coordinator Description

The purpose of this document is to describe the roles and responsibilities of the National Dental PBRN Program Coordinator that have to do with study development and study implementation. Located at UAB, a portion of this person's time is allocated to assist with meetings of the Study Team held for each network study. These roles and responsibilities include:

- schedule and send communications for each monthly Study Team meeting;
- following preparation of the meeting agenda by the Westat Study Manager and SPI, distribute the agenda and accompanying packet for each monthly Study Team meeting;
- take minutes for each meeting and distribute to the Westat Study Manager and SPI for their initial approval, followed by distribution to the other attendees as the Study Team meeting.