
**Practice-Based Research Networks:
Designed to gather “real-world”
evidence**

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Dental Practice-Based Research Networks - Purpose

Establish infrastructure to:

- **Answer questions facing general dental practitioners in the routine care of their patients**

 - **Strengthen knowledge base for making clinical decisions**
 - **Observational studies**

 - **Clinical trials**

 - **Establish/use a flexible, adaptable electronic network/platform for connectivity, data sharing, & communication within and between dental and medical networks**
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Dental Practice-Based Research Networks

- **Ideas to be generated by practicing dentists and dental hygienists (i.e., practitioner-investigators)**
 - **Primary objectives:**
 - **Conduct 16-22 short-term clinical studies over 7 years**
 - **Emphasis on effectiveness of oral health treatment & disease prevention**
 - **Clear & clinically meaningful outcomes**
 - **Secondary objective: Provide data on disease and treatment trends and obtain estimates of the prevalence of less common conditions**
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Dental Practice-Based Research Networks

- **Establishes partnership between practitioners and experienced researchers**
 - **PBRN's conduct research in the real world of dental practice**
 - **Draw on experience & insight of practitioners to help identify and frame questions**
 - **Findings likely to be immediately relevant to dental practice**
 - **Results are likely to be accepted and implemented in dental practice**
 - **Certain types of studies can be conducted more cost-effectively than if supported as stand-alone studies**
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Dental Practice-Based Research Networks

- **Many questions faced by dentistry are most appropriately addressed in practice-based dental settings**
 - **Dental PBRNS may implement protocols developed by one another**
 - **To prevent duplicity of studies in NIDCR portfolio, Dental PBRNs provide NIDCR a summary of prospective protocol prior to development**
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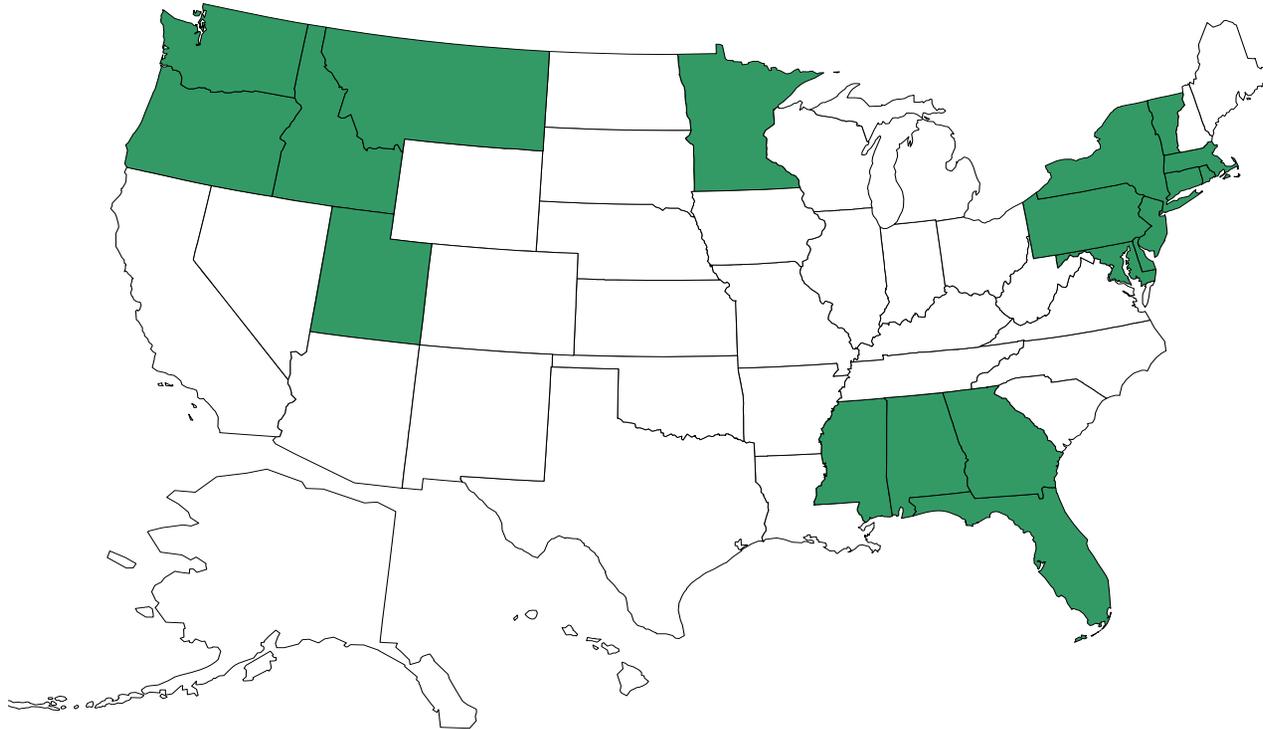
Dental Practice-Based Research Networks

- At least **100 dental** practices per Dental PBRN will be recruited to participate during the **first year** of operations.
 - Each PBRN will involve large numbers of practitioner-investigators in at least **two population centers**.
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In their first six months, By State, General Dentists Have Been Recruited by these PBRNs:

- **Alabama** 
- **Connecticut** 
- **Delaware** 
- **Florida** 
- **Georgia** 
- **Idaho** 
- **Maryland** 
- **Massachusetts** 
- **Minnesota** 
- **Mississippi** 
- **Montana** 
- **New Jersey** 
- **New York** 
- **Oregon**  
- **Pennsylvania** 
- **Rhode Island** 
- **Utah** 
- **Vermont** 
- **Washington** 
- **Other states contribute smaller numbers of participants.**

Six-month Snapshot of PBRNs' Membership, by State:



Note: Other states are currently contributing smaller number of participants;
Expansions to other states are planned.

Dental Practice-Based Research Networks – Organization

- **Network Chair**
 - **Coordinating Center**
 - **Executive Committee**
 - **NIDCR Staff**
 - **Protocol Review Committee**
 - **IRB**
 - **DSMB (Phase III Trials)**
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Dental Practice-Based Research Networks – Network Chair

- **Overall scientific and administrative leadership**
 - **Operations and fiscal management**
 - **Chair Executive Committee**
 - **Organizes Protocol Review Committee**
 - **Recruits, selects, trains, certifies & monitors practitioner- investigators and staff**
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Dental Practice-Based Research Networks – Network Chair

- **Stimulates and solicits ideas for study**
 - **Arranges meetings and conference calls**
 - **Fosters and maintains communication between all segments of PBRN**
 - **Assumes leadership role in manuscript preparation**
 - **Hosts annual research meeting of participating practitioner-investigators**
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Dental Practice-Based Research Networks – Coordinating Center

- **Coordinates DSMB activities**
 - **Monitors adverse event reporting**
 - **Assists in developing recruitment materials**
 - **Prepares site visit reports**
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Dental Practice-Based Research Networks – Coordinating Center

- **Develops, maintains, and provides quality assurance of data bases & data collection**
 - **Assures interoperability of data collection, data standards, & informatics systems**
 - **Provides data analyses**
 - **Assists in developing**
 - Study protocols**
 - Statistical design for studies**
 - Manual of procedures for each study**
 - IRB submissions / DSMB reports**
 - Informed consent procedures**
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Dental Practice-Based Research Networks – Executive Committee

Composition

- **Network Chair**
 - **PI of Coordinating Center**
 - **5-6 elected practitioner-investigators**
 - **NIDCR staff**
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Dental Practice-Based Research Networks – Executive Committee

Responsibilities

- **Executive and administrative arm of PBRN**
 - **Main governing body of PBRN**
 - **Prioritizes research topics for submission to Protocol Review Committee**
 - **Reviews and approves protocols prior to submission to Protocol Review Committee**
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Dental Practice-Based Research Networks – Practitioner Investigators

- **PBRN trained and certified dentists and dental hygienists engaged in daily practice**
 - **From more than one state and population center**
 - **Representative of gender / racial / ethnic distribution of PBRN region**
 - **Limited number may be from outside U.S. if standard of dental care is comparable to that in U.S**
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Dental Practice-Based Research Networks – Practitioner Investigators

Responsibilities

- **Elect representatives to Executive Committee**
 - **Suggest studies to Executive Committee**
 - **Contribute to protocol development**
 - **Conduct studies in their practices**
 - **Conform to IRB, DSMB, HIPAA regulations**
 - **Contribute to manuscript preparation**
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Dental Practice-Based Research Networks - Review

- Ideas for individual studies proposed to the PBRN Executive Committee
 - After review by the PBRN Executive Committee, all protocols must be approved by:
 - Protocol Review Committee
 - IRB
 - DSMB for Phase III Trials
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Protocol Review Committees (PRC)

■ Responsibility

- The Scientific-merit of each protocol is assessed by a group of independent experts – the PRC.
- Uniform review criteria used across all three PBRNs
- PRC meetings are confidential.

■ Membership

- One expert from each of the five core areas of expertise
 - Up to two content-specific experts, as necessary, for the specific protocol under consideration.
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Each PRC contains a core of experts:

- **Biostatistics (voting)**
 - **General Dentistry (voting)**
 - **Medical PBRN Administration (voting)**
 - **Clinical Investigation (voting)**
 - **NIDCR Programs (ex officio; non-voting)**
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Protocol Review Committees (PRC)

- **Each Network Chair nominates members**
 - **NIDCR approves PRC membership**
 - **Core members serve staggered terms to facilitate membership continuity**
 - **In general, a two-year renewable term limit is recommended.**
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PRC Protocol Review Process:

- **Open Session of PRC**
 - PBRN presents 15-minute overview of proposed study to PRC.
 - PRC members clarify issues with PBRN

 - **Closed Session of PRC**
 - PBRN members do not participate
 - Scientific deliberation lead by PRC chair
 - Review outcome is determined

 - **PRC and PI session**
 - Communication of review outcome and recommendations (if applicable to PBRN)
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Protocol Outcomes:

- **Approval:**
 - Requires majority vote of PRC members
 - **Disapproval with Recommendation for Resubmission**
 - **Disapproval and Not Recommended for Resubmission:**
 - Requires unanimous vote of PRC members
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