Rapid Disruptions: Understanding the Dental Information Networks around Alternative Nicotine Products and Other Clinical Needs Relevant to Patient Care and Health

NIDCR Protocol Number: 15-078-E

NIDCR Grant Number: U19-DE-22516

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Version Number: 2.0

December 21, 2017

STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the Code of Federal Regulations (CFR) on the Protection of Human Subjects (45 CFR Part 46), and the National Institute of Dental and Craniofacial Research (NIDCR) Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects' protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and guidelines.

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LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
ANP	Alternative Nicotine Products
CC	Coordinating Center
CFR	Code of Federal Regulations
CRF	Case Report Form
DHHS	Department of Health and Human Services
FFR	Federal Financial Report
GCP	Good Clinical Practice
GPI	Grant Principal Investigator
GT	Georgia Institute of Technology
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
KN	Knowledge Networks
MOP	Manual of Procedures
N	Number (typically refers to participants)
PBRN	National Dental Practice-Based Research Network
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
QA	Quality Assurance
QC	Quality Control
RAS	Regional Administrative Sites
RC	Regional Coordinator
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
SPI	Study Principal Investigator
US	United States

PROTOCOL SUMMARY

Title: Rapid Disruptions: Understanding the Dental Information Networks around Alternative Nicotine Products and Other Clinical Needs Relevant to Patient Care and Health.

Précis: This study will characterize and examine the structure, content, and pathways of clinical information in the dental information ecosystem. It will also give attention to disruptive events that impact knowledge and information diffusion through a focus on alternative nicotine products (ANPs). The study will address the clinical information-seeking networks (both formal and informal) of dentists and hygienists.

This is a multi-methodological 39-month study that will be conducted in the National Dental Practice-Based Research Network (National Dental PBRN). The study will involve one round of survey implementation, on-going bibliometric data collection and web scraping, as well as one round of feedback interviews via telephone.

Objectives: Primary: The primary objective is to develop an understanding of information diffusion pathways and patterns within the dental community that harnesses scholarly and high profile media outlets.

The primary outcome measures are:

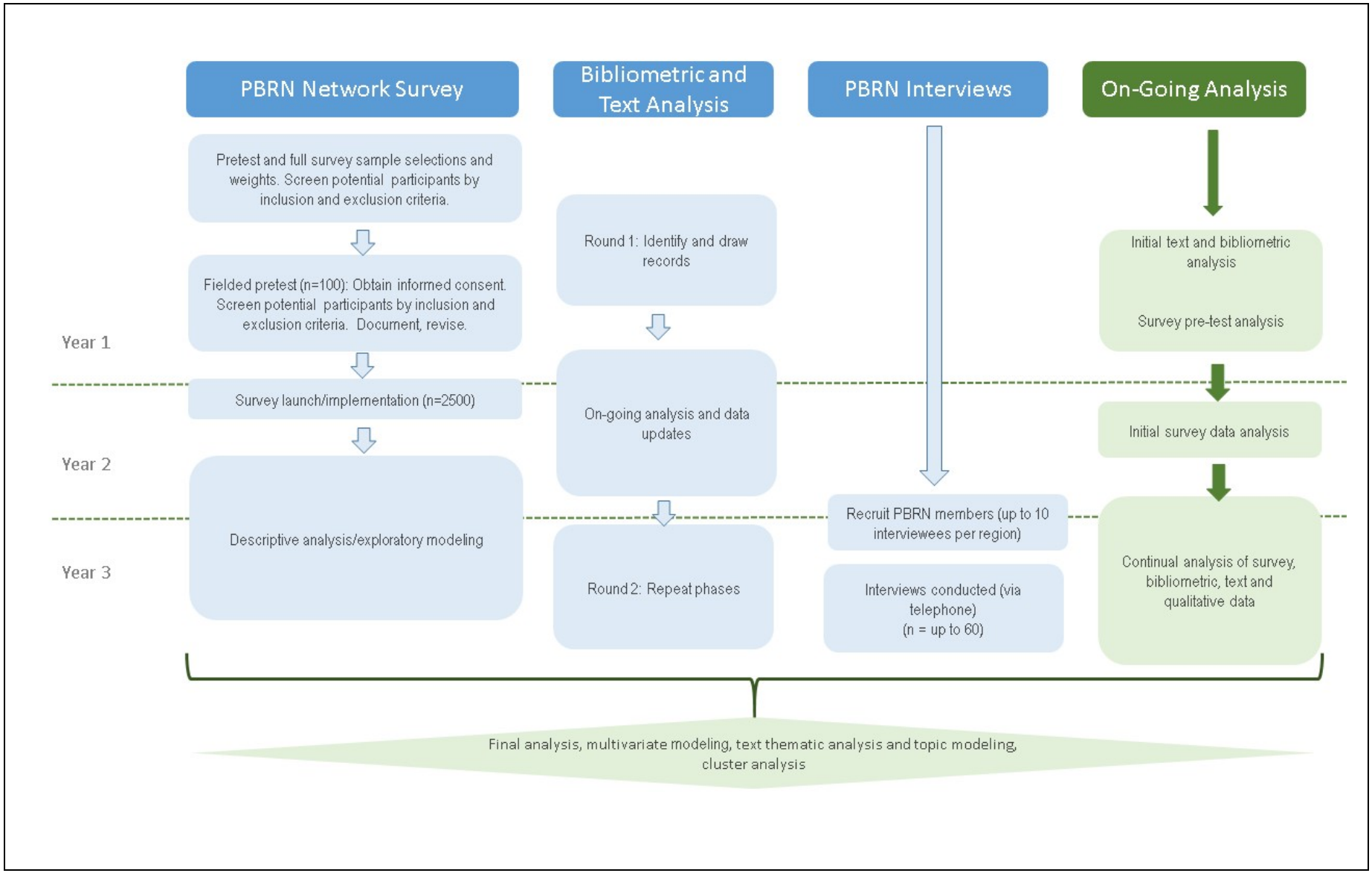
1. Information production and availability on topics of interest to the dental practitioner community: detailed categorization of academic and select public media/dental network information.
2. Information pathways: detailed categorization of the direction and channels through which research results and other novel clinical information diffuses to and among dentists, and how that varies by topical area.

The secondary objectives of this study are to:

1. Understand practitioners' information needs, and interpersonal and other information sources for clinical information, including related to alternative nicotine products (ANPs).
2. Understand dental practitioners' clinical information needs, and interpersonal and other information sources

	for clinical information search and access patterns, and preferences. The important secondary outcome measure is dental practitioner information networks: identification of interpersonal and other sources of information and advice regarding clinical areas where practitioners seek outside information, including (but not limited to) ANP, perceived information preferences, quality/credibility assessment, and interests. The secondary outcome measures will be ascertained through a survey to assess practitioners' information needs and sources.
Population:	For the online survey, the study will draw a stratified sample from the approximately 4000 eligible National Dental PBRN practitioners to complete the survey with the goal of obtaining 2500 respondents. Interviews will include up to ten participants per region for individual phone interviews (up to 60 practitioners total in all regions).
Number of Sites:	One site: Georgia Institute of Technology
Study Duration:	Approximately 39 months
Subject Participation Duration:	Survey respondents will participate in an online survey, each lasting approximately 20-30 minutes. Interview participants will participate for approximately 45-60 minutes.
Estimated Time to Complete Enrollment:	Approximately 24 months

SCHEMATIC OF STUDY DESIGN:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

The size and breadth of the network of resources available to clinical dentists has grown exponentially in recent years. Most notably, and similar to many knowledge-based professions, the onset of the digital age resulted in a virtual explosion of internet-based information, and information providers, relevant to dental practice. But, digital media does not explain all of the growth in resources and information availability. The number of academic dental journals has also recently grown from 46 publications in 2003 to 83 in 2012 (Jayaratne and Zwahlen, 2015). Professional associations are adapting to changing constituent needs and developing new communication mechanisms to disseminate information, including distillations of research findings, to their memberships. Dentists, and dental hygienists, travel to a growing set of continuing education options where they gain knowledge from instructors as well as colleagues. Overall, the system of supplying, and accessing clinical dental information has evolved from a simple networks of knowledge providers and users, to a complex ecosystem that is dynamic and multi-layered. Metaphors and frameworks based on ecological and biological systems have been used in an array of disciplines to describe and categorize the interwoven nature of complex networks (Pickett and Cadenasso, 2002). Most relevant to evidence-based dentistry is the notion of a "knowledge ecosystem" which "fosters the dynamic evolution of knowledge interactions between entities to improve decisions-making and innovation" (Briscoe, 2010, p 42). Yet, little is known about the behavior of this dental knowledge ecosystem and how information diffuses across it.

The continued advancement of clinical care in dentistry depends on the successful application of research and new knowledge relevant to the profession. In fact, innovation in materials, the creation of new products, and other advances can have important impacts on the dental community and the practice of dentistry. This is also the potential impact for products that are less clearly central to dental impacts. For example, the rapid uptake of alternative nicotine products (ANPs), especially e-cigarettes, have been labeled as a "disruption" to not only the market, but also the health care community.[11] ANPs are not only new products where the use patterns are changing and unclear, but there is also considerable uncertainty about the composition, ingredients, and potential health effects (oral and otherwise) of these currently unregulated products. While market share is decreasing somewhat from the remarkably strong surge in the past five years, e-cigarette sales are still expected to grow by 56% in 2016, and to be a $50 billion market by 2030 (Vaperranks, 2015; Wall Street Journal, 2015).

The growing trends and popularity of ANPs (including e-cigarettes, hookahs and other similar products) may present a particular challenge for the dental community given the lack of scientific evidence about the effects of these products, and increasing media scrutiny/debate on their use and safety. A cursory search for "e-cigarettes" at the initial stage of this project on Google Scholar showed 4,460 results, of which 1,370 were in the last year alone (web search, May 14, 2014). Today, this same search yielded 7,330 results (web search, December 7, 2014). To date, much of the focus has been on behavioral (e.g., product use, smoking cessation) and economic

[1] http://cornerstonecapinc.com/2014/03/e-cigarettes-a-positive-disruption-to-the-market-and-health-or-a-distraction2/

issues (e.g., market growth), while results on actual health effects are not yet available. The Centers for Disease Control and Prevention (CDC) estimates that the use rate of e-cigarettes by youth alone doubled in 2012 from the previous year to reach 10%, indicating a potential risk to a non-trivial portion of the population. As research to address health effects is funded, more information will be available in future years. Given the attention to the products, issues surrounding their regulation, market growth, use, and possible effects, it is also likely that information in the popular press will also continue to grow. This rapidly moving information environment presents a very real challenge for the dental practitioner, for ANPs and possibly for other new products or discoveries in the future.

The purpose and process of information seeking is in itself complicated, and not necessarily tightly focused on the reduction of uncertainty (Case, 2012). For many areas in dentistry, the wealth of information available that could enhance clinical dental practice and related outcomes is coupled with a general uncertainty on how to maximize knowledge transfer within the dental community. For disruptive areas, however, the landscape is even less understood. In today's technology-rich environment, practitioners have the ability to access information and engage in "conversations" with other professionals in online forums, webinars, video conferences and other modalities. However, these modalities do not necessarily provide insight into the quality of information transmitted in the forum. This is important since recent research also suggests that information from online forums may not be translated into clinical practice applications (Funkhouser et al, 2012) and that print resources may resonate more with certain groups of dentists (Botello-Harbaum, et al 2013).

Despite deficits of information about ANPs and other areas relevant to dental practice, recent research indicates that even when clinical evidence is high, dental practitioners do not always follow disseminated clinical care or best-practice guidelines for preventive, diagnostic, and/or treatment procedures (Hannes et al, 2008). This may be partially an artifact of relatively passive strategies (e.g., emails, websites, and publications) designed to spread this information and influence the adoption of efficacious treatments, or it may be explained by other factors specific to the assessment of the information itself, or reluctance to seek out information via publication sources (Case, 2012; Kajermo, 2000). Given the vast unknowns specific to the use and effects of ANPs, these existing information deficits are likely exacerbated. The mismatch of information availability and clinical adoption in dentistry points to the need to conduct exploratory research to understand where, how, and from whom practitioners acquire dental-related information, the quality of that information, and how it influences their practice behavior. This is relevant to ANPs, but also more broadly to other information needs.

2.2 Rationale

Overall, clinicians, researchers, professional associations and other dental professionals are faced with a significant challenge of culling through print and online materials in order to access and assess clinical research findings relevant to their dental practice. Information gatekeepers face the challenge of distilling information in meaningful and accessible ways in order to maximize reach and utility of clinical evidence. For many areas in dentistry, the wealth of information that is available is coupled with a general uncertainty on how to maximize knowledge transfer in the dental community. Ultimately, the development of internet

technology and the digitalization of information, as well as the virtual explosion of information sources available have created a completely different dental information ecosystem.

The challenge of diffusing, as well as accessing, information is likely to grow. For example, given the intense market growth and related concerns about health effects of ANPs, the information landscape with regard to these products is likely to change, potentially rapidly. The purpose of this project is to address the current and growing information sources and networks in the dental community specific to ANPs, and how that functions within dental information networks. To address this, it is important to not only understand how information networks around these products develop, but also how they are anchored in (or different from) existing dental information networks. Does the information flow of a “new challenge” on the dental horizon follow traditional information paths? Or, is it “disruptive” where new and unknown information sources are important? Does it mimic other recent disruptive products, important discoveries (not related to ANP) or other similar products?

An important role of the National Dental PBRN is to develop knowledge that might be generalizable and improve adoption of evidence-based practices in the dental community. One premise is that more active and targeted approaches may be more effective and efficient for the dissemination and implementation of evidence-based practices to health professionals, including dental practitioners. For example, studies in dentistry, and in other professional settings show that personal connections (professional networks) are critical vehicles for sharing and adoption of knowledge (Gabbay, 2004.) Yet, how this may be implemented and maximized is uncertain due to the general lack of broad understanding of the information needs, preferences, and communication networks in the dental community.

2.3 Potential Risks and Benefits

This is an observational study; research participants will contribute to the survey and focus group components of the study. There are minimal risks associated with this project. Bibliometric records and web-scraping involves information in the public domain.

2.3.1 Potential Risks

Risks for the proposed study are minimal. Practitioners may not feel comfortable answering particular questions on the survey. As such, they will have the option of skipping any question that they do not feel comfortable answering (no question is required). As with any study, there is the possibility of breach of confidentiality. Appropriate precautions will be taken and procedures will be followed to maintain confidentiality. These include use of unique study codes for participants, and password-protected computers for data storage. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed. Individual identifier numbers that are linked to interviewee names will be stored separately from the actual notes, and password protected servers at Georgia Tech will be used to store data. Data will only be accessible to research personnel and will be stored and coded according to guidelines set forth by the Georgia Tech Institutional Review Board.

2.3.2 Potential Benefits

Participation in the study will provide no direct benefit to participants but will provide the dental community with several benefits. First, this study will enable the National Dental PBRN to understand the development, content, and dissemination of information around “disruptive” ANPs. Second, with better information on the types and patterns of resources that develop around these ANPs, and an indication of the issues that dental practitioners face in seeking and processing this information, the National Dental PBRN can be better positioned to inform and assist the dental community. Third, as information networks are better understood, the results of the study will inform the structure and communication flow of the National Dental PBRN by improving distribution of information that is effective, efficient and provider-centered. Fourth, by illuminating knowledge use and information sources, and perceptions and reputation of various sources in the dental community, the results of the study may help to inform other studies of dental knowledge communities.

3 OBJECTIVES

3.1 Study Objectives

Primary: The primary objective is to develop an understanding of information diffusion pathways and patterns within the dental community that harnesses scholarly and high profile media outlets.

Secondary: The secondary objectives are to:

1. Understand dental practitioners' information needs, and interpersonal and other information sources for clinical information, including related to ANPs.

2. Understand dental practitioners' clinical information search and access patterns, and preferences.

3.2 Study Outcome Measures

3.2.1 Primary Outcomes

The primary outcome measures are as follows:

1. Information production and availability on topics of interest to the dental practitioner community: detailed categorization of academic and select public media/dental network information.
2. Information pathways: detailed categorization of the direction and channels through which research results and other novel clinical information diffuses to and among dentists, and how that varies by topical area.

The primary outcomes for this study will be accomplished through a significant "big data" text mining and analysis process. This aspect of the project will draw from a number of text-based sources, including academic, social media, and print-based products to address knowledge diffusion in dentistry. (Note: this portion of the project does not involve human subject data and will not require IRB approval).To do this, the study will collect and categorize academic and public media coverage on current clinical research areas, with special attention to emerging areas regarding ANPs/use. This type of data mining will focus on ANPs but also use data mining to iteratively identify diffusion patterns of other topics relevant to clinical needs. This iteration will be critical to explaining the information ecosystem across various dental information and knowledge sources. The expectation is that through a detailed and comprehensive topic modeling approach, the study will reveal diffusion patterns across major content areas (to be discovered in the text mining process) as well as for other areas identified by the study team and executive committee.

Topic modeling involves the identification of content themes using a text-mining approach. Bibliometric and other media data will be coded and categorized according to source, information need, type, and other characteristics in order to identify the information direction and pathways. A goal of this analysis will be to develop a typology of information needs and sources relevant to the dental community. Historical knowledge pathways analysis on the dissemination patterns of a previous disruptive product (to be determined through initial bibliometric analysis and in consultation with our clinical team members) will also be performed. For example, our team has discussed medication-related osteonecrosis of the jaws (MRONJ) as an option. Given the richness of the text data, we do not want to set boundaries at this time, with the exception of prioritizing clinical issues (as opposed to practice management issues, for example). Because this approach relies on secondary data, it also allows us to examine current and dynamic knowledge pathways specific to ANPs as well as to other topical areas relevant to clinical dentistry. This bibliometric analysis will enable us to determine whether there are any common patterns in information dissemination and use for disruptive new products or discoveries. It will also allow us to trace the information pathways from the clinical/peer-reviewed research literature to other information sources readily accessible to dentists and hygienists (professional conferences, professional publications, gray literature and other media).

3.2.2 Secondary Outcomes

The secondary outcome measure is as follows:

1. Dental practitioner information networks: identification of interpersonal and other sources of information and advice regarding clinical areas where practitioners seek outside information, including (but not limited to) ANP, perceived information preferences, quality/credibility assessment, and interests.

This secondary outcome measures will be ascertained through a survey to assess practitioners' information needs, sources, preferences, and issues relevant to the identification and assessment of available information regarding ANPs, and to other issues self-identified in the survey by respondents. The survey will also address prevalence of ANP use observed in clinical practices.

Other variables of interest include the following:

- Professional characteristics and demographics (age, year since graduation, specialty, practice size, gender, race, geographic region, etc.) Source: existing PBRN enrollment data/survey data.
- Information sources for clinical questions where dental practitioners must seek information outside of their own expertise, as well as ANPs. Information sources include published literature, internet and other resources, sources within professional organizations, as well as interpersonal resources. Source: survey data.
- Social networks (attribute data regarding inter-personal networks of dentists and hygienists, resources and social capital provided through these networks (and variation across descriptive variables of interest) Source: survey data.
- Perceived information preferences, perceived quality/appropriateness assessment. Source: survey data.

- Information search patterns (how are sources selected and in what order). Source: survey data.
- Items addressing the awareness, concern, and response of the dental community to the emergence of ANP, screening for ANPs in their practice. Source: survey data.

Interviews will also be conducted later in the study that will allow for additional exploration of issues discovered through the analysis, providing useful qualitative insight into dental information search patterns and resource networks.

1. Information gaps and barriers to access: assessment of the facilitators and barriers to obtaining and valuing information about ANP and other clinical information.

The study will conduct a series of interviews in the PBRN in order to collect detailed qualitative data on the implications for our study findings, concerns among dental practitioners regarding ANP use among patients, and the quality and accessibility of information on relevant clinical issues/problems as well as ANPs. Our focus will be on the facilitators and barriers to obtaining quality research-based information and integrating it into daily practice routines.

4 STUDY DESIGN

This is a multi-methodological 39-month study involving an online survey, a series of interviews, multiple stages of bibliometric data collection, and web scraping for non-academic publications in key media sources and online dental discussion boards. The strength of this approach is that it blends self-reported behavioral and attitudinal data (survey and focus group data) with evidence of knowledge transfer data (publication and other print/media/discussion board) in order to provide a detailed analysis of dental knowledge needs, sources, available resources and networks, and knowledge pathways. Primary data collection will involve a survey of dental practitioners enrolled in the PBRN network (dentists and dental hygienists) and a series of interviews to be conducted via telephone.

Practitioner Survey:

To be eligible for the survey, practitioners must be enrolled in the National Dental PBRN and have completed an Enrollment Questionnaire. An estimated 4000 dentists and hygienists will be eligible to complete the survey (survey population frame), from which an estimated sample of roughly 415 practitioners per region (N=2500) will be drawn. The survey sample will be stratified by PBRN region, dentist/hygienist, as well as gender, race, specialty and practice type. The details of this sampling stratification will be refined once the PBRN enrollment survey data are provided to the study team by Westat. The survey will be implemented during the 1st year of study implementation, after the first round of bibliometric and web scraping. The duration of survey implementation is anticipated to be approximately five months. Development and administration of the questionnaire survey is detailed in Section 7.1.

Survey Pilot-Test Phase

The Study Team will pilot the survey with approximately 100 practitioners (approximately 50 dentists and 50 hygienists). The purpose of the pilot/field-test phase of the study is to identify possible issues with the study procedures and materials that might cause difficulty in implementation or compromise the quality of data that are collected. It builds on the previously completed cognitive testing process and serves as a broader check on the instrument and related response patterns across different groups of respondents in a true field-tested environment. It will also be used to check response patterns and response variance and allow us to address any instrumentation problems particularly with key variables. It is expected that minor modifications to the survey may be made after the fielded pilot test. These changes should not cause significant delay since all survey administration is managed internally at Georgia Tech, allowing any modifications to be made in an efficient manner. Data collected in the pilot phase of the study will not be included in the full study dataset unless only very minor or no changes occur after this phase. The pilot phase testing is anticipated to be approximately two months.

Interviews

One cycle of interviews (up to 60 total) will be conducted via telephone in approximately year 3 of study implementation. The qualitative inquiry will support our synthesis of findings across the survey and bibliometric aspects of the project. Interviews will allow us to develop rich data on

specific issues that arise via the survey data, as well as to delve into issues specific to ANPs. This will allow us to compile reactions to the findings and provide an assessment of current challenges in understanding how to address ANP use in practice. For the interviews, we will use purposive sampling, recruiting eligible participants through the Regional Coordinators (RCs) from each region. This purposive sampling will be informed by survey results. For example, if the survey results show distinct patterns by demographic or practice-based characteristics, then we will recruit individuals according to those differences. At the very least, interviewees will be selected to reflect the demographic (age, gender, practice type) characteristics of the PBRN network membership. We envision up to ten interviews per region, for a total of up to 60 individuals overall. Study team members will work with regional coordinators to invite eligible participants to engage in the interviews. Each of the interviews will last approximately 45-60 minutes.

Bibliometric literature search and Web-Scraping:

An important complement to the collection of primary data from PBRN dental practitioners is an intensive examination of the information network/ecosystem that generates, provides, and in some cases filters research findings to the dental community. This aspect of the study will draw from a spectrum of text-based sources. Bibliometric searches specific to select clinical areas (those included in the survey) as well as ANPs will be conducted in this process. The Web scraping process will also occur during this time. By definition, information diffusion through social media has intense rapidity. Therefore, monitoring of social media, listservs, and other web sources will be conducted periodically throughout the study implementation phase and be flexible enough to respond to new developments (such as regulation or other related issues) reports, and publications. The bibliometric search will be repeated at various intervals during the study process. Bibliometric records and web-scraping involve information in the public domain, and do not involve any primary data collection from human subjects. Academic publications will be drawn from the PubMed/Web of Science/Medline sources. Nonacademic literature will be acquired through a series of “web scraping” procedures using keywords and sources to compile literature in high circulation sources, as well as materials acquired through our team and contacts with the American Dental Association and other professional groups. *As these bibliometric and publication-based data sources do not involve primary data collection from human subjects, they are not described further in this protocol*. The results from this analysis will inform the interpretation of the survey results, and will also stand on their own as a distinct set of study findings from this project work.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Inclusion Criteria

In order to be eligible to participate in this study, a practitioner must meet all of the following criteria:

- Is enrolled in the National Dental PBRN as a limited or full participation network member;
- Is a practitioner or a dental care professional and has completed an Enrollment Questionnaire;
- Is licensed in the U.S. to treat patients, treats patients in the U.S. on a recurring basis, and maintains an active practice address at which he or she can be contacted;

5.2 Strategies for Recruitment

5.2.1 Practitioner Recruitment

Eligible practitioners for the survey will be identified based on the criteria noted from their responses on the PBRN Enrollment Questionnaire. All eligible practitioners will first receive an alert letter informing them of the survey, followed by a study invitation email inviting them to participate in the study. The alert letter and invitation will include a link to the electronic version of the survey. Based on previous regional PBRN questionnaire studies, we anticipate a response rate of approximately 80%. Calls will be made as needed with the Regional Coordinators (RCs) to review contact information for eligible practitioners, and assist in response encouragement. For the interviews, we will use purposive sampling, recruiting eligible participants from each region. Study team members will work with RCs to invite eligible participants to engage in the interviews.

Practitioners will be reimbursed $50 for participation in the survey and $50 for participation in an interview. This is a single survey questionnaire study with interviews; retention strategies are not applicable.

5.3 Subject Withdrawal

Practitioners may choose not to participate in the study and/or withdraw voluntarily from the study for any reason at any time without penalty. Practitioners who withdraw from the study will not be replaced.

5.4 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party. If the study is prematurely terminated or suspended, the study principal investigator (SPI) will promptly inform the IRB and will provide the reason(s) for suspension or termination.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to study participants.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY SCHEDULE

6.1 Practitioner Survey

Eligible practitioners will be identified based on their responses to the Enrollment Questionnaire and will be invited to complete an online questionnaire over a period of approximately 3-4 months during the first year of study implementation. Agreement to enter the survey will indicate tacit consent per Georgia Tech IRB regulations (a standard waiver of consent for web-based surveys).

The invitation mail/email schedule will be detailed in the Data Management Plan.

6.2 Practitioner Interviews

Study team members will work with regional coordinators to identify and invite up to 60 eligible participants to engage in the telephone interviews.

Each interview will last approximately 45-60 minutes. Telephone interviews will occur during year 3 of study implementation.

7 STUDY PROCEDURES/EVALUATIONS

7.1 Survey Development and Administration

Practitioner Survey Development

This survey was developed by our study team, a group with expertise in questionnaire development and implementation, and was internally tested by the clinicians who are part of the team. Following the development of the survey, the instrument was reviewed by Program Officials at the NIDCR. The survey has been programmed in the Survey Management System (SMS) and uploaded and is ready for field pretesting.

Cognitive Interviewing

Cognitive testing of the survey instrument was completed in early December 2015. Team members Drs. Melkers, Isett, and Frantsve-Hawley conducted six 60 minute interviews with three general dentists and three hygienists. The Executive Committee review of the instrument was also very helpful, and resulted in specific changes to the instrument. This process provided an opportunity to review the survey in detail with dentists and dental hygienists, and to also test its timing. These practitioners were invited to the complete the online survey via a unique ID and password. Once completed, they were provided with a printout of the blank survey codebook to facilitate conversation with the team member who interviewed them about their experience. Interviewers reviewed their responses to a completed survey, and probed to assess possible respondent problems in understanding questions, recalling necessary information, and/or reporting accurately. Based on team discussion, a small set of questions were also flagged for specific probes during these interviews. We asked participating practitioners how relevant they thought the items in the draft survey were to addressing information related to ANP and other disruptive products, and whether any issues relevant to ANP were not addressed in the survey. From the Executive Committee review and the detailed cognitive interviews, minor wording changes to add clarity and understandability were made. Completion time for the survey was 20-34 minutes.

Website and Survey Testing

The survey was programmed in Sawtooth Software (licensed by Georgia Tech) and has been uploaded to an online site for testing. The study team performed extensive internal testing of the survey website, including internet browser compatibility. Study team members (e.g., SPI, National Network Director (NND), Regional Directors, Statistician and Regional Coordinators (RC)) will be given the opportunity to externally test the website prior to administration with study participants.

Survey Pilot- testing

The online version of the survey will be administered to approximately 100 practitioners to assess the reliability of the survey. Based on cognitive interviewing, the survey is expected to take 20- 30 minutes to complete. The field test will provide a more complete understanding of survey timing prior to the full implementation.

Survey Content

Some information will be collected from the National Dental PBRN Enrollment Questionnaire (e.g., demographics and practice characteristics) and linked to participants' responses to the study survey. Topical areas addressed in the survey are detailed in Section 3.

Survey Administration

Eligible participants, i.e., dentists and hygienists, will be identified from their responses to the network's enrollment questionnaire. Skip logic may also be incorporated in the survey in order to provide an additional screening mechanism.

A waiver of documentation of signed informed consent will be required for participants to enter the survey. Consistent with regulations outlined by the Georgia Tech (GT) IRB, information about the study as well as their rights as participants, will be provided to all eligible practitioners in the postal invitation mailing as well as in the electronic survey prior to the start of the survey questions.

The survey will be administered by the Georgia Tech team. The survey process will follow Dillman (2000) survey methods, and will include an alert letter sent via US mail as well as an email notice, and periodic reminder emails. All eligible participants will receive a study invitation alert letter one week in advance of the email notification and invitation to the survey. Participants will receive multiple reminders to complete the survey. Participants will receive a unique user ID and password that will be needed to enter the survey. Due to the complexity of the survey, as well as cost constraints, a paper survey will not be used as an alternative.

If no feedback is received or the participant does not complete the survey after multiple follow up attempts over a period of three to four months, it is assumed the practitioner has declined to participate in the study.

7.2 Interview Guide Development and Administration

Interview Guide Development

Decisions on this process for development and the content of the focus group interview guide will be reached at a later date, and will depend upon observed trends and findings from other study activities. *No interviews will be conducted until IRB approval for those data collection instruments is complete.*

Interview Administration

Informed consent procedures will be performed prior to participation in the interview. Consistent with regulations outlined by the Georgia Tech (GT) IRB, information about the study will be provided to all eligible practitioners in an email invitation to participate in the interview, as well as verbally from the interviewer prior to the start of the interview. Interviews will be conducted by study team members. Interviews will be audio-recorded and transcriptions will be completed for each interview. Data from the interview transcriptions will be coded and analyzed for thematic issues using NVivo software (text analysis software). Transcriptions will be conducted as

interviews are completed in order to manage work flow. Study team members (Melkers, Hicks, Isett) will do spot checks on the transcriptions to ensure quality and completeness.

Each interview will last approximately 45-60 minutes and will be conducted in an invited telephone conference call format to maintain confidentiality. The specific instrument for these interviews will be developed following the completion of the initial analysis of the study survey data.

8 ASSESSMENT OF SAFETY

8.1 Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems involving risks to participants.

8.1.1 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.2 Reporting Procedures

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Per Georgia Tech guidelines, investigators are required to *report to the Institutional Review Board within ten days of its occurrence* any serious problem, serious adverse event, or other outcome that occurs more frequently or with greater severity than anticipated. Further, if any event(s) cause the suspension, whether temporary or permanent, of a research study involving human subjects, the IRB must be informed within ten days. Such reports to the IRB must

describe the adverse events' relevance and significance to the study and whether there is a change in the risk of participation.

Any reported harm as a result of study participation will be reported to the Georgia Tech Office of Research Integrity. Guidelines on reporting violations or harm are as follows:

> *"Anyone with a concern about any aspect of research involving human subjects at Georgia Institute of Technology or who wants to report a violation of these Policies and Procedures may contact the Institutional Official/VPR, the IRB Chair, any IRB member, a Research Associate, or the Executive Director or Associate Director of Research Integrity Assurance. Concerns may also be emailed to irb@gatech.edu. Reports made to the Office of Research Integrity Assurance will be delivered to the IRB Chair and the Institutional Official/VPR for further action."*

To satisfy the requirement for prompt reporting, unanticipated problems will be reported to NIDCR within 2 weeks of the investigator becoming aware of the problem.

- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: rho_productsafety@rhoworld.com

9 STUDY OVERSIGHT

The GPI and SPI will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The SPI will review the data for safety concerns and data trends at regular intervals, and will report to the IRB and NIDCR any unanticipated problem, protocol deviation, or any other significant event that arises during the conduct of the study, per the IRB's reporting time-frame requirements. To ensure data integrity, the SPI and study team will adhere to quality management processes (see Section 13).

10 CLINICAL SITE MONITORING

Clinical site monitoring will not occur for this study, however data monitoring will occur. The SPI is responsible for launching the survey, performing interviews, and collecting data received through the survey and interviews. Quality assurance (QA)/Quality Control (QC) activities associated with data collection and processing will be outlined in the data management plan (DMP). The SPI will ensure that the quality and integrity of study data and data collection are maintained.

11 STATISTICAL CONSIDERATIONS

11.1 Study Hypotheses

Due to the exploratory nature of the data gathered in this study, no formal hypothesis will be presented here.

11.2 Sample Size Considerations

A stratified sample of eligible PBRN members will be invited to participate in the survey. Detailed analysis of the composition of the PBRN membership list will be necessary to make the final sampling plan. Our probability sampling approach will be used with the goal of achieving a confidence level of 95% with a 3-5% margin of error. Our preliminary expectation is that approximately 500 individuals from each of the six regions will be selected for the survey sample. For regions with lower enrollment, the population in that region will be included in the survey. This number will provide sufficient flexibility to address sampling stratification needs. The final sampling plan will be completed once the PBRN enrollment questionnaire data and full contact list are available to the SPI.

We will use a cluster-based sampling approach to ensure comparability across PBRN regions, together with a stratified random sample of participants in order to ensure a representative sample that would be consistent with the characteristics of the population of practicing dentists and dental hygienists (Blair and Blair, 2014). As part of our research questions, and motivated by theoretical and empirical work on under-represented groups and organization theory, any sampling strategy would require at a minimum stratification by gender, age, race/ethnicity, dental specialization, practice type, PBRN region, and rural/urban status.

An important part of the analytical plan will also include an assessment of non-response bias based on PBRN composition. Depending upon the results of this analysis, additional follow-up with particular respondents may be required.

The study team will also consider a data weighting approach depending on the composition of the PBRN membership. If this is necessary, the sample weights for the survey will be developed and included in the final data set.

11.3 Final Analysis Plan

Analysis plan for Primary Objectives:

Primary objective: Primary: The primary objective is to develop an understanding of information diffusion pathways and patterns within the dental community that harnesses scholarly and high profile media outlets.

The analysis for the primary objective will involve text-based tracing and impact analysis, using a range of bibliometric research approaches. As noted earlier in this protocol, the details on the bibliometric and other text-based analyses are not included in this protocol but will be developed in a separate white-paper document. Vantage Point Software (already licensed and available at Georgia Tech) and other software will be used to facilitate this analysis. This analysis is based on publicly-available data and will not require IRB approval.

For the web-scraping data as well as analysis specific to the relationship of research literature to various diffusion mechanisms, we will develop a series of efficient optimization algorithms for estimating the diffusion models from a set of identified dental clinical areas (once again, to be identified in the bibliometric data, for example, osteonecrosis of the jaw and bisphosphonates), as well as the ANPs. Functionally, this will involve the coding and identification of information "kernels" and relational aspects of the data. Overall, the analytical plan for the bibliometric and other text-based data is anticipated to be primarily descriptive and provide a detailed depiction and categorization of information pathways and organizational roles in the overall dental knowledge ecosystem. This analysis will assess primary knowledge sources and the various filters and diffusion mechanisms in the dental community. Details specific to the analysis of the survey data are provided in the section below on secondary analysis.

11.3.1 Proposed Secondary Analyses

Analysis plan for Secondary Objectives:

Secondary: The secondary objectives are to:

1. Understand dental practitioners' information needs, and interpersonal and other information sources for clinical information, including related to ANPs.

2. Understand dental practitioners' clinical information search and access patterns, and preferences.

Analyses will focus on how professionals access information on problems relevant to their practices, and the temporal aspects of their search processes. The primary survey data collected will provide the data necessary to understand the relationships described in section 3.1 (Study Objectives).

Variables of interest for this analysis will include:

- Professional characteristics and demographics (age, year since graduation, specialty, practice size, gender, race, geographic region, etc.) Source: existing PBRN data/survey data.
- Information access patterns (what sources are accessed and in what order) Source: survey data.
- Social networks (attribute data regarding inter-personal networks of dentists and hygienists, resources and social capital provided through these networks (and variation across descriptive variables of interest) Source: survey data.

Various combinations of demographic characteristics may be associated with different patterns of information seeking behavior. If the dental population can be understood as a handful of groups with different preferences, timescales, and interests in their information gathering, organizations seeking to better disseminate information to dentists and hygienists can tailor their strategies to more effectively serve each group. The analysis will be using clustering techniques to develop profiles of different types of dental information seekers. Given the exploratory nature of this study, the analyses will be mainly descriptive, but will include multivariate models to explore correlation and association. For example, correlations of research experience, study team involvement and other professional engagement variables with interpersonal clinical resources will be useful in understanding differences across the populations. Practice location and region with ANP awareness and screening may reveal geographic factors specific to ANP concerns. Descriptive statistics will include central tendency measures such as mean, median, and mode, as well as cross tabulations to address the inter-relatedness of our variables of interest. We are especially interested in whether there are significant differences in many of our key variables of interest across groups (dentists/hygienists as well as other variables noted in discussion on sample stratification). Comparison of means tests and cross tabulations will provide useful descriptive data.

In addition to the descriptive analysis, we anticipate developing a series of multivariate regression models appropriate to the data set and questions. These models will be developed based on appropriate theoretical literature given the specific research question addressed, prior studies, and input from our study team. For example, dentist/hygienist, practice size, gender, and involvement in research and professional communities will be appropriate independent variables to test on overall interpersonal network size and resources. Among others, some key dependent variables of interest include: ANP screening behavior, ANP knowledge, clinical network resource levels, breadth of research engagement/cosmopolitanism (Bozeman and Corley, 2004) multiplexity and homophily of clinical information sources and resources (Lin et al., 2001), and others. Exploratory regression models will allow us to control for practice size, region, gender, and other variables on level of awareness of ANPs, ANP screening, as well as knowledge network resources. We foresee use of a variety of regression approaches in the analysis of the survey and membership data such as OLS, negative binomial, logit and probit modeling, as well as network analysis models, where appropriate.

12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Source data/documents will be maintained by the SPI for this study. The electronic survey will be available via a SMS (Sawtooth Software). After a participant submits the electronic survey, data will be available in the SMS.

Notes and audio recordings will be generated from the interviews, and will be considered the source documentation for these sessions. Recordings will be transcribed, and participant identifiers will be kept separate from text data files.

Only study personnel i.e., the SPI and her team (CITI certified members and IRB approved) will have access to data elements during the study timeframe. All research documents will be stored on password-protected Georgia Tech servers, which are securely backed-up once per day. Data files will be kept in a secure, locked file in the SPI's office. A copy will also be stored on a password-protected GT network computer only accessible to the SPI.

13 QUALITY CONTROL AND QUALITY ASSURANCE

For the QA/QC activities associated with survey data collection and processing, the SPI will develop a DMP and data cleaning protocol in which the specific data QA/QC procedures will be provided. The procedures will include the development of regular response pattern and bounced email/contacts checks in the SMS and the processes related to the data manual review and discrepancy management. A detailed codebook that documents all variable and respondent data cleaning and variable creation will also be developed in this study.

The SPI will directly supervise and implement the online survey, including the updating of participant response status, follow-up email reminders, and response confidentiality and completion. For the QA/QC activities associated with interviews, the SPI and her team will develop a DMP and data cleaning protocol in which the specific data QA/QC procedures will be provided. This will involve a detailed coding schematic for coding and verifying text-based data and analysis. It will also involve a process for checking completeness, accuracy and verification of interview transcription and related data maintenance to ensure data coding quality and consistency. Any errors or discrepancies will be remediated.

14 ETHICS/PROTECTION OF HUMAN SUBJECTS

14.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46. All team members who are involved in data collection and analysis will be listed on the protocol and will have completed and been CITI-certified for Human Subjects Research. Completed certifications will be provided to the Georgia Tech IRB office. Graduate students hired on this project will need to be certified and added to the protocol prior to their commencement of work.

14.2 Institutional Review Board

This protocol has been reviewed and approved by the Georgia Institute of Technology Institutional Review Board (IRB) as a preliminary step. Once the NIDCR approves this protocol, it will be amended at Georgia Tech. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

14.3 Informed Consent Process

Survey

The standard waiver of documentation of signed informed consent for internet-based surveys will be requested for this study. Consistent with regulations outlined by the GT IRB, informed consent language will be provided on the entry page to the survey and will indicate that consent is provided if the respondent chooses to enter the survey with the user ID and password that they have been provided (tacit consent).

Interviews

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. For interviews, information about the study will be provided to all eligible practitioners in an email invitation to participate in the interviews as well as verbally from the interviewer prior to the start of the interview. The consent process will involve a discussion of risks and possible benefits of study participation. A consent form describing in detail the study procedures and risks will be given to the practitioner. Consent forms will be IRB-approved, and the practitioner is given the document to read and review. The study team member conducting the interview will explain the research study to the practitioner and answer any questions that may arise. A copy of the informed consent document will be given to the practitioner. The SPI will maintain a copy of the signed consent documents if applicable.

14.4 Exclusion of Women, Minorities, and Children (Special Populations)

Minors will not be enrolled in this study. Dentists and hygienists of any gender or racial/ethnic group may participate if they meet eligibility criteria. We expect to oversample women and underrepresented minority groups.

14.5 Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Only study personnel (i.e., SPI and study team with CITI certification) will have access to identified research study data. Participants will be assigned unique identification numbers (i.e., practitioner IDs (PID)) that will be used to maintain study records and organize data files. A file linking participants' names and contact information with their unique identification number will be kept in a password-protected file on a password protected server account of the SPI, and will be destroyed after the study analysis is completed in accordance with regulations set forth by the IRB. The study team will follow Georgia Tech guidelines for the storage and confidentiality of data. The study team will also comply with NIH rules regarding data storage post project completion.

15 DATA HANDLING AND RECORD KEEPING

The study team is responsible for ensuring the accuracy and completeness of the data reported, and following the data collection and management procedures as outlined in the DMP. Access to raw study data will be limited to IRB-approved/CITI certified team members. At a later date, de-identified data may be provided to other researchers.

15.1 Data Management Responsibilities

The SPI will work closely with her team to ensure that the electronic surveys are being collected appropriately and confidentiality is being maintained according to the protocol specified procedures. The SPI and her graduate student will take responsibility for maintaining the PBRN contact list and enrollment questionnaire data, survey response data, and transcription data from the interviews. For the survey and interview participants, the data reported in the network's Practitioner Database will be reviewed by the Georgia Tech study team to identify eligible practitioners for this study. All data reported in the SMS will be checked by the study team for completeness and consistency.

All data manipulation and cleaning will be documented accordingly. A data cleaning protocol will be developed in order to ensure consistency in preparation of the final survey data set. A detailed survey data codebook will contain information and basic descriptive statistics on all variables in the survey. It will also include non-response bias analysis and full details on data recoding and new variable construction. Because some variables from the enrollment questionnaire will be merged with the final survey data set, details on included variables will also be documented in the survey codebook.

Interview data will be maintained in a series of text-based files with appropriate version control. The Georgia Tech graduate student with primary responsibility for data coding will maintain a file management and related documentation system to ensure data confidentiality and quality control. A detailed protocol for text data coding will be developed in order to ensure data coding quality and consistency.

15.2 Data Capture Methods

A sample of eligible network practitioners will be invited to participate in this study.

Sawtooth Software will be the SMS for the survey portion of this study. Preliminary testing and review of data fields were conducted in the initial programming and online launching of the survey. For the full field launch, a dedicated server will be used in order to ensure a responsive data system with no delays for survey respondents. Sawtooth Software employs a series of backup servers that provides additional data security. Regular backups of the data during the fielded survey period will be done once per week by the SPI as an additional precaution. The reports with the summary of the data completion by the participants will be made available on the network web site if requested.

For the interviews, sessions will be audiorecorded (using digital recorders) and subsequently transcribed. Recorded files will be in .WAV format and maintained on the Georgia Tech computer

system in a password protected and limited access server. Transcriptions will be completed in Microsoft Word and maintained in the same secure access server. Digital files will be destroyed following final transcription and related verification processes for confidentiality purposes. Interview data will be analyzed in NVivo (text analysis software).

15.3 Types of Data

Data consist of:

- participants' responses to the electronic survey;
- recordings, interviewer notes, and related transcripts from interviews;
- bibliometric records drawn from the Web of Science and PubMed/Medline;
- web-scraping data.

15.4 Schedule and Content of Reports

The Georgia Tech team will continually monitor survey responses during the fielded survey period. Response reports will be provided to NIDCR for review every two weeks and upon request. Regular monitoring of responses and tracking of response patterns by region will also be communicated to regional coordinators in order to assist with their communication with regional members.

Final data analysis reports that address the objectives of the study will be produced by the study team for NIDCR review at the conclusion of each major data collection phase (survey, bibliometric, text analysis and web-scraping). The content of these reports will be determined by the SPI and other study team members. .

15.5 Study Records Retention

Study records will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the National Institutes of Health (NIH). Data files will be kept in a secure, locked file in the SPI's office, and a copy will also be stored on a password-protected GT network computer only accessible to the SPI.

As outlined by IRB regulations, identifier data will be destroyed in an appropriate and safe way (e.g., and files will be securely deleted from computers) approximately three years after the grant FFR has been submitted to NIH.

15.6 Protocol Deviations

A protocol deviation (PD) is any noncompliance with the clinical study protocol or GCP principles. The noncompliance may be on the part of the participant, SPI, or study staff. As a result of deviations, corrective actions may be developed by the study staff and should be implemented promptly. All deviations from the protocol must be addressed in study subject source documents and reported to NIDCR and the local IRB, according to their requirements.

Any PD that is reportable to an IRB must also be reported to NIDCR. NIDCR defers to the IRB for reporting time-frame requirements. Once a PD has been reported to an IRB, action must be

taken to report the deviation to NIDCR. If the IRB overseeing the study protocol requires annual reporting of PDs to their IRB, that reporting frequency is acceptable to NIDCR.

16 PUBLICATION/DATA SHARING POLICY

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. All study personnel are required to read in its entirety and agree to abide by the network's "Data Analysis, Publications, and Presentations Policies" document. The current version of this policy is always kept at the network's public web site at http://nationaldentalpbrn.org/publication.php.

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