

Isolation Techniques Used When Performing Root Canal Treatment

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NIDCR Grant Principal Investigator:

Gregg Gilbert, DDS, MBA

Study Principal Investigator:

Gregg Gilbert, DDS, MBA

Institution:

University of Alabama at Birmingham

NIDCR Program Officials:

Dena Fischer, DDS, MSD, MS
Don DeNucci, DDS, MS

NIDCR Medical Monitor:

Holli Hamilton, MD, MPH

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STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the 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.

Grant Principal Investigator/Study Principal Investigator/South Central Regional Director:			
Signed:	_____	Date:	_____
	Name: Gregg H. Gilbert, DDS, MBA		
	Title: Professor and Chair University of Alabama at Birmingham		

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LIST OF ABBREVIATIONS

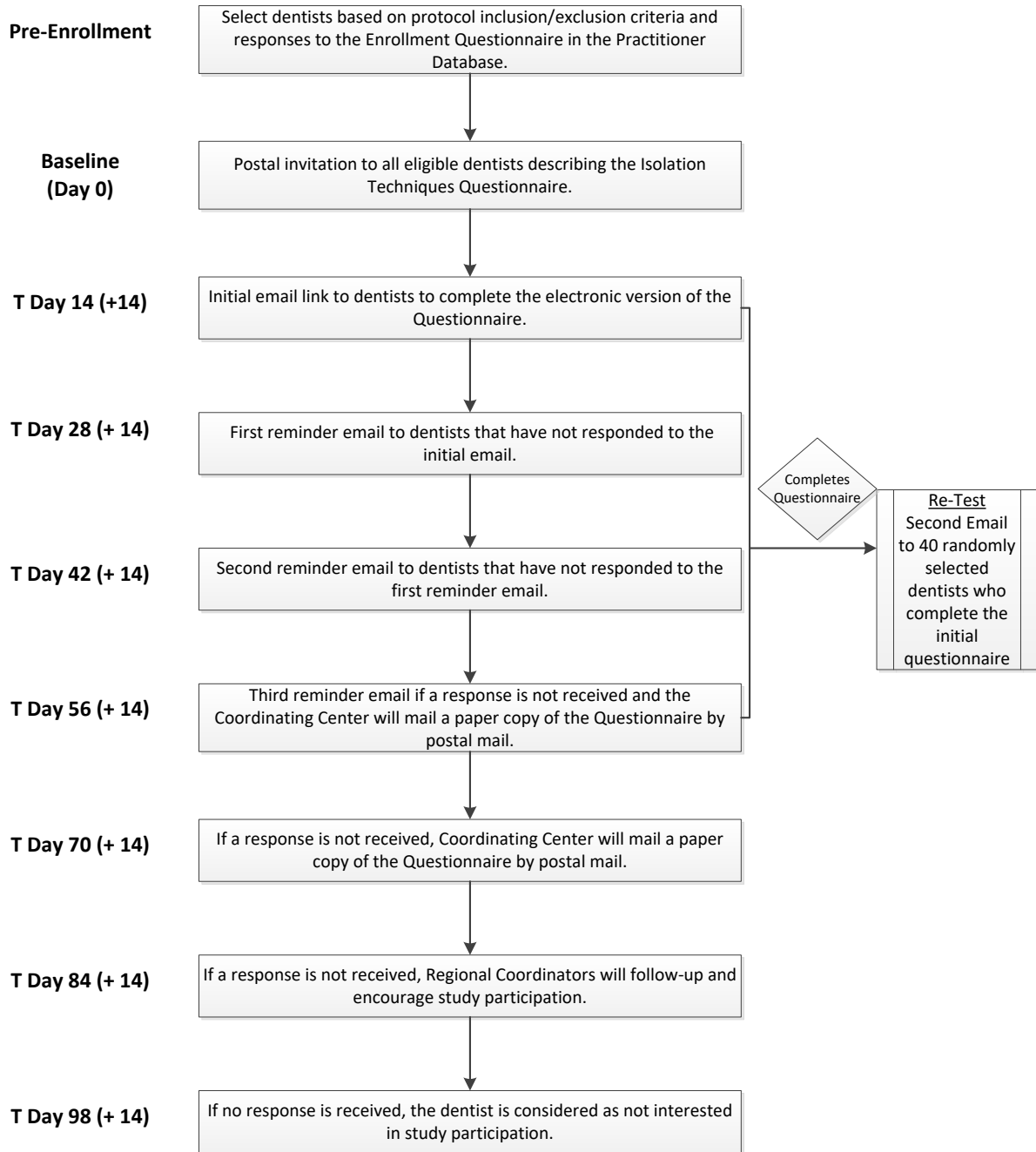
AAE	American Association of Endodontists
AE	Adverse Event/Adverse Experience
CC	Coordinating Center
CDM	Clinical Data Manager
CFR	Code of Federal Regulations
DMP	Data Management Plan
FFR	Federal Financial Report
GCP	Good Clinical Practice
GPI	Grant Principal Investigator
HPDG	HealthPartners Dental Group
IRB	Institutional Review Board
N	Number (typically refers to participants)
NIDCR	National Institute of Dental and Craniofacial Research
NIH	National Institutes of Health
NND	National Network Director
OHRP	Office for Human Research Protections
PBRN	Practice-Based Research Network
PDA	Permanente Dental Associates
PID	Practitioner ID
QA	Quality Assurance
QC	Quality Control
RCs	Regional Coordinators
RCT	Root Canal Treatment
SAE	Serious Adverse Event/Serious Adverse Experience
SMS	Survey Management System
SOP	Standard Operating Procedure
SPI	Study Principal Investigator
T	Time/Time Point
UAB	University of Alabama at Birmingham
US	United States

PROTOCOL SUMMARY

Title:	Isolation Techniques When Performing Root Canal Treatment.
Précis:	The proposed study will assess isolation techniques used when performing root canal treatment among dentists in the National Dental Practice-Based Research Network (PBRN). A questionnaire will be administered to eligible dentists in the network. The questionnaire will assess dentists' use of various isolation techniques when performing root canal treatment; identify factors associated with use (or non-use) of rubber dams when performing root canal treatment (RCT); and identify factors associated with rubber dam use during RCT. Pending findings from this study, a follow-up study will be conducted utilizing clinical vignettes to gain a more in-depth, contextualized understanding of how and why dentists may or may not use rubber dams when performing RCT. Collectively, this information will help identify implementation strategies needed to increase the appropriate use of rubber dams during RCT among dentists in the network.
Objectives:	<p>The primary objective of this study is:</p> <ul style="list-style-type: none">• To quantify the self-reported use or non-use of rubber dams when performing RCT. <p>The secondary objective of the proposed study is:</p> <ul style="list-style-type: none">• To identify factors associated with use or non-use of rubber dams for RCT.
Population:	The study will invite all general dentists who are members of the National Dental PBRN and who reported on their Enrollment Questionnaire that they do at least some root canal treatment to participate in the study.
Number of Sites:	A projected number of approximately 2000 National Dental PBRN general dentists are eligible based on their responses to the network's Enrollment Questionnaire.
Study Duration:	Approximately 9 months for enrollment, data collection and data analysis.
Subject Participation Duration:	Each participant (dentist) will need up to 30 minutes to complete the questionnaire administered as part of this study.

Estimated Time to Complete Enrollment:	Approximately 3 - 4 months
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Schematic of Study Design:



T = Time Point

1 KEY ROLES AND CONTACT INFORMATION

Grant Principal Investigator:	Gregg H. Gilbert, DDS, MBA Professor and Chair University of Alabama at Birmingham 1720 2nd Ave. S. School of Dentistry, SDB 109 Birmingham, AL 35924 Phone: (205)-975-8886 Fax: (205)-975-0603 Email: ghg@uab.edu
Study Principal Investigator	Gregg H. Gilbert, DDS, MBA Professor and Chair University of Alabama at Birmingham 1720 2nd Ave. S. School of Dentistry, SDB 109 Birmingham, AL 35924 Phone: (205)-975-8886 Fax: (205)-975-0603 Email: ghg@uab.edu
Statistician	Ellen Funkhouser, DrPH Associate Professor Division of Preventive Medicine School of Medicine University of Alabama at Birmingham Medical Towers 611 1717 11th Ave. S. Birmingham, AL 35205 Phone: (205) 934-1120 Fax: (205) 934-4959 Email: emfunk@uab.edu
Medical Monitor:	Holli Hamilton, MD, MPH Senior Medical Officer NIH/NIDCR/DER 6701 Democracy Blvd., Room 638 Bethesda, MD 20892 Phone: (301)-451-3852 Cell: (240)-477-7713 Email: hamiltonho@mail.nih.gov

<p>NIDCR Program Officials:</p>	<p>Dena Fischer, DDS, MSD, MS Phone: (301)-594-4876 Email: dena.fischer@nih.gov</p> <p>Don DeNucci, DDS, MS Phone: (301)-451-5096 Email: denuccid@nidcr.nih.gov</p> <p>NIH/NIDCR/DER 6701 Democracy Blvd., MSC 4878 Bethesda, MD 20892</p>
<p>Data Coordinating Center:</p>	<p>Westat 1600 Research Blvd., WB294 Rockville, MD 20850 Dr. James Korelitz, Director Phone: (301)-294-4414 Fax: (240)-294-4494 Email: jameskorelitz@westat.com</p>
<p>Institutions:</p>	<p>Western Region (Region #1) Administratively based at the Kaiser Permanente Center for Health Research, Portland Oregon Lisa Waiwaiole, Regional Coordinator Kaiser Permanente Center for Health Research 3800 N. Interstate Ave. Portland, OR 97227-1110 Phone: (503) 335-2454 Fax: (503) 335-6311 Email: lisa.ann.waiwaiole@kpchr.org</p> <p>Midwest Region (Region #2) Administratively based at the HealthPartners Research Foundation in Minneapolis, MN Emily Durand, Regional Coordinator HealthPartners Institute for Education and Research 8170 33rd Ave. S. MS 21111R Minneapolis, MN 55445 Phone: (952) 967-7404 Fax: (952) 967-5022 Email: emily.c.durand@healthpartners.com</p> <p>Southwest Region (Region #3) Administratively based at the University of Texas Health Science</p>

	<p>Center at San Antonio in San Antonio, TX Stephanie C. Reyes, Regional Coordinator STRF MC 8258 8403 Floyd Curl Drive San, Antonio, TX 78229 Phone: (210) 562-5654 Fax: (210) 562-4137 Email: reyess@uthscsa.edu</p> <p>South Central Region (Region #4) Administratively based at the University of Alabama at Birmingham in Birmingham, AL Andrea Mathews, Program Manager Department of Clinical and Community Sciences School of Dentistry, SDB 114 1720 2nd Ave. S., SBD Box 39 Birmingham, AL 35294-0007 Phone: (205) 934-2578 Fax: (205) 996-2172 Email: ahmathews@uab.edu</p> <p>South Atlantic Region (Region #5) Administratively based at the University of Florida in Gainesville, FL Deborah McEdward, Regional Coordinator University of Florida P.O. Box 100415 Gainesville, FL 32610 Phone: (352) 273-5848 Fax: (352) 273-7970 Email: dmcedward@dental.ufl.edu</p> <p>Northeast Region (Region #6) Administratively based at the University of Rochester in Rochester, NY Pat Ragusa, Regional Coordinator Eastman Institute for Oral Health 625 Elmwood Ave., Box 683 Rochester, NY 14620 Phone: (585) 275-5780 Fax: (585) 273-1237 Email: pat_ragusa@URMC.rochester.edu</p>
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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Rubber dam use during orthograde root canal treatment (RCT) has been shown to improve occupational safety, reduce likelihood of infection, improve treatment effectiveness, minimize risk of contamination of the root canal system, and reduce accidental ingestion or injury during RCT.¹⁻⁶ Moreover, rubber dam use during RCT is endorsed by several professional societies and practice organizations, including the American Association of Endodontists (AAE), which considers it the standard of care.⁴

Despite strong empirical evidence, general dentists do not always use rubber dams during RCT.⁷⁻⁹ In a study conducted by Hill and Rubel (2007) among a sample of 164 general dentists in the United States (US), 11% of general dentists reported never using a rubber dam during endodontic procedures and only 58% reported always using a rubber dam during endodontic procedures. A recent study by Anabtawi and colleagues¹⁰ found similarly low rates of rubber dam use during RCT among general dentists in the National Dental Practice-Based Research Network (NDPBRN). Among the 449 general dentists in the U.S. who reported doing RCT, 45.2% (n = 203) used rubber dams for all (i.e., 100%) RCTs, 40.1% (n = 180) used it for 1-99% of RCTs, and 14.7% (n = 66) never used it during RCT (i.e., 0%). Significant associations between rubber dam use and type of practice (i.e., solo private practice, group private practice, HealthPartners Dental Group [HPDG]/Permanente Dental Associates [PDA], public health practice, or other) were observed, such that general dentists in HPDG or PDA reported higher rates of rubber dam use during RCT than those in other practice types. Year of dental school graduation was also significantly associated with rubber dam use, such that general dentists who graduated more recently reported higher rates of rubber dam use than those who graduated less recently. Moreover, a significant association was observed between region and rubber dam use, such that general dentists in the PDA or West regions were more likely to use rubber dams during RCT than those in other regions. In an ordinal logistic regression, only type of practice (i.e., HPDG/PDA vs. non-HPDG/PDA) was significantly associated with rubber dam use during RCT. Gender and race/ethnicity of the general dentist was not associated with rubber dam use during RCT.¹⁰

Although several studies have documented relatively low rates of rubber dam use during RCT among general dentists, only a few studies have focused on identifying factors associated with suboptimal rubber dam use. A survey conducted with 300 Irish general dental practitioners found difficulty in application and use of alternative procedures (e.g., throat pack) as key barriers to using a rubber dam to perform RCT.¹¹ Another questionnaire study with 164 general dentists in the US identified barriers to rubber dam use such as dentists' beliefs that rubber dams are inconvenient,

unnecessary, or too time intensive, patients' refusal or dentists' perception of patients' refusal.^{12,13}

2.2 Rationale

Although some, albeit limited, information exists regarding barriers toward consistent and appropriate rubber dam use when performing RCTs, we currently do not have information on the use of various isolation techniques — including rubber dams — used when performing RCTs among dentists currently enrolled in the National Dental PBRN. Moreover, while it is known that dentists in the previous cycle reported suboptimal usage of rubber dams when performing RCTs, we have little knowledge on what factors are associated with the National Dental PBRN dentists' suboptimal usage of rubber dams. In an effort to increase the appropriate use of rubber dams when performing RCTs, the following needs to be accomplished:

1. Determine if there is a gap between recommended use of rubber dams when performing RCTs and actual use of rubber dams when performing RCTs in practice;
2. Identify factors associated with use and non-use of rubber dams when performing RCTs; and
3. Understand how specific factors identified above influence the use or non-use of rubber dams when performing RCTs.

In **Phase I**, a questionnaire will be administered to:

1. Quantify the self-reported use or non-use of rubber dams when performing RCT; and
2. Identify factors associated with use or non-use of rubber dams for RCT.

In **Phase II**, clinical vignettes will be developed and administered to:

1. Understand how specific factors identified in Phase I influence the use or non-use of rubber dams when performing RCT.

Phase II of the study will be conducted pending outcomes of Phase I. Thus, for the remainder of the study protocol, only Phase I is discussed. A brief summary of the proposed Phase II can be found in Appendix A.

Hypotheses

We hypothesize that certain dentist-level variables (e.g., gender, race/ethnicity, years since graduation, attitudes, beliefs, skills) and practice-level characteristics (e.g., practice size, private vs. group practice) will be statistically significantly associated with rubber dam use when performing RCTs. However, given the dearth of literature on factors associated with suboptimal rubber dam usage, we cannot hypothesize which

particular variables will be associated with greater or lesser use of rubber dams when performing RCTs. Thus, our hypotheses are largely exploratory, as follows:

Hypothesis 1: There is a gap between recommended use of rubber dams when performing RCTs (100%) and actual self-reported use of rubber dams when performing RCTs ($\leq 100\%$).

Hypothesis 2: Specific dentist- and practice-level characteristics are associated with use of rubber dams when performing RCTs.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Risks for the proposed study are minimal. Participants 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.

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. All study documents (e.g., paper questionnaires, electronic data files) will be kept in a locked file only accessible to research and Coordinating Center (CC) staff members. Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

2.3.2 Potential Benefits

Benefits of the proposed study include the opportunity for participants to contribute to our understanding of factors associated with use of rubber dams when performing RCTs. Although they may not benefit directly from participation in this study, information they provide will help in better understanding of factors associated with the use of rubber dams when performing RCTs, with the ultimate goal of improving the quality of dental care and patient health outcomes.

3 OBJECTIVES

3.1 Study Objectives

The primary objective of the proposed study is:

- To quantify the self-reported use or non-use of rubber dams when performing RCT.

The secondary objective of the proposed study is:

- To identify factors associated with use or non-use of rubber dams for RCT.

3.2 Study Outcome Measures

3.2.1 Primary Outcome

The primary study outcome is the self-reported use or non-use of rubber dams when performing RCT (details in section 11). This will be analyzed two ways:

- a. As a dichotomous variable (100% or perhaps $\geq 95\%$, namely, virtually all the time); and
- b. As a continuous variable.

Both a and b above will be assessed separately for type of tooth involved (anterior, premolar, molar) and whether or not tooth has gingival/subgingival caries.

3.2.2 Secondary Outcomes

Secondary outcome measures include dentist- and practice- level characteristics as well as participant (dentist) root canal practices, use of other isolation techniques when performing RCTs and factors associated with use or non-use of rubber dams for RCT. The dentist- and practice- level characteristics, participant root canal practices and use of other isolation techniques when performing RCTs will be assessed with the primary outcome measure to determine the association of these factors with use or non-use of rubber dams when performing RCTs. Factors associated with use or non-use of rubber dams for RCT will be assessed by construct with the primary outcome measure.

Dentist-level characteristics include the following and will be assessed by the Enrollment Questionnaire (e.g., demographic characteristics) and the proposed study questionnaire:

Participants' demographics

- Age;
- Gender;

- Race;
- Ethnicity; and
- Year of graduation from dental school.

Participants' RCT practices and use of other isolation techniques when performing RCTs [Questions 6-22]

- Number of root canals performed per month: Overall, by tooth involved (anterior, premolar, molar), whether or not tooth has gingival/subgingival caries;
- Participants' self-reported use of other isolation techniques (e.g., cotton roll/gauze, Isolite™); and
- General RCT practices: Preferred techniques (endodontic instrumentation, obturation); preferred canal irrigation; preferred materials (sealers, canal fill).

Participants' knowledge, attitude/motivation and perceived skills for using rubber dams when performing RCTs

- Participants' knowledge about rubber dam use (e.g., correct or incorrect information about usefulness of rubber dams when performing RCTs [Questions 23-34: information construct]);
- Participants' attitudes toward rubber dam use [Questions 35-43: attitude construct]; and
- Participants' perceived skills for using rubber dams when performing RCTs (e.g., perceived difficulty or ease with which one is able to use rubber dams when performing RCTs [Questions 44-55: skills construct]).

Practice-level characteristics include the following and will be assessed by participants' responses to the Enrollment Questionnaire (and updated with any changes as noted in this study's questionnaire):

Participants' practice characteristics

- Type of practice (e.g., private, public, managed care); and
- Geographic region of practice.

4 STUDY DESIGN

This is a National Dental PBRN cross-sectional questionnaire study and consequently it is multicenter in that numerous dentists will be approached to participate in the study. The study will include approximately 2000 dentists who are members of the National Dental PBRN.

Questionnaire Development

Appendix B contains the isolation techniques questionnaire that will be administered via Internet and/or postal mail to all eligible dentists. The questionnaire has been developed based on input from NIDCR program officers and study team members with content expertise in isolation techniques used to perform RCTs (including rubber dams). Development of the questionnaire has also been informed by psychological and organizational theories of behavior change as well as implementation frameworks for use of evidence-based practices.¹⁴⁻²¹

Test-Retest Questionnaire

The online version of the questionnaire will be administered twice to a subset of participants to assess the test-retest reliability of the questionnaire. Participants who complete the online version of the initial questionnaire will be sent a second online questionnaire request by email approximately two weeks after receipt of the first completed questionnaire.

Participants will be randomly selected for the retest. The selection will be based on the response rate to the initial survey. Each participant will be given approximately one week to complete the re-test. If the re-test is not completed within the timeframe, the link to the re-test questionnaire will be disabled. This process will be continued until 40 participants complete the re-test. The questionnaire will take up to 30 minutes to complete each time.

Pilot Test Website and Questionnaire

The CC's IT team will perform extensive internal testing of the website, including internet browser compatibility. Study team members (e.g., Study Principal Investigator (SPI), National Network Director (NND), Statistician and Regional Coordinators [RCs]) will also be given the opportunity to externally test the website prior to administration with study participants.

Administer Questionnaire

Following pilot testing of the website, the questionnaire will be administered to all eligible dentists. Dentists will have an opportunity to complete an electronic or paper version of the questionnaire in order to increase participation rates. For details of questionnaire administration, please see sections 5.3, 6.2, 6.3. and 7.1.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Participant Inclusion Criteria

Dentists must meet all of the inclusion criteria in order to be eligible to participate in the study based on their responses to the network's Enrollment Questionnaire:

- Is a current limited or full participation member of the National Dental PBRN;
- Is a general dentist;
- Is currently practicing/seeing patients; and
- Performs RCTs.

5.2 Participant Exclusion Criteria

All dentists meeting any of the following criteria will be excluded from participation:

- Is a current information-only participation member of the National Dental PBRN; and/or
- Is unwilling or unable to follow study procedures.

5.3 Strategies for Recruitment and Retention

Recruitment

Eligible dentists for the study will be identified based on the criteria noted from their responses on the Enrollment Questionnaire. All eligible dentists (i.e., N = approximately 2000) will first receive a study invitation postal mailing from the CC team inviting them to participate in the study. The invitation will indicate that the dentist will receive an email with a link to the electronic version of the questionnaire. Dentists will have an opportunity to complete an electronic or paper version of the questionnaire in order to increase participation rates. Based on previous regional PBRN survey studies, we anticipate a response rate of approximately 60-70%.

Compensation

Participants will be reimbursed \$50 for participation in the study. If a participant completes the re-test of the questionnaire, then an additional \$50 will be provided.

Retention

This is a cross-sectional survey study; retention strategies are not applicable.

5.4 Subject Withdrawal

Participants may choose not to participate in the study and/or withdraw voluntarily from the study for any reason at any time without penalty.

5.4.1 Reasons for Withdrawal

Dentists may choose not to participate in the study and/or may be withdrawn if it is determined that the dentist meets an exclusion criterion that precludes further study participation.

5.4.2 Handling of Subject Withdrawals

It is anticipated that dentists will not be replaced since all eligible dentists will be invited to participate in the study.

Although unlikely, responses from dentists who do not meet eligibility criteria but who still are asked to complete the questionnaire will be removed prior to statistical analyses. Exclusions will be based on completion of the questionnaire which are a “0” response to how many RCTs the dentist currently performs or if the dentist is no longer a general dentist (i.e., the respondent has become a dental specialist since completing the Enrollment Questionnaire).

5.5 Premature Termination or Suspension of Study

The 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 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 Screening

Based on the inclusion/exclusion criteria described above, as well as a recent review of data from the Enrollment Questionnaire, it is anticipated that approximately 2,000 dentists will be eligible for the proposed study. This, however, may be subject to change as enrollment in the National Dental PBRN increases between study protocol development and study start date. Eligible dentists will be identified from their responses to the Enrollment Questionnaire. Although unlikely, responses from dentists who do not meet eligibility criteria but who still are asked to complete the questionnaire will be removed prior to statistical analyses. Exclusions will be based on completion of the questionnaire which is a “No” response to if the dentist currently performs one or more RCTs per month or if the dentist is no longer a general dentist (i.e., the respondent has become a dental specialist since completing the Enrollment Questionnaire).

Informed Consent

A waiver of documentation of signed informed consent for participants who complete the electronic or paper questionnaire will be requested. Consistent with regulations outlined by the University of Alabama (UAB) IRB, information about the study will be provided to all eligible dentists in the postal invitation mailing as well as in the electronic or paper questionnaire prior to the start of the survey questions. Completion of the questionnaire will provide tacit consent.

6.2 Enrollment/Baseline

Eligible dentists will be identified based on their responses to the Enrollment Questionnaire.

An initial study invitation postal mailing will be sent to eligible dentists by the CC. The invitation will include information regarding the study. The postal letter and envelope will be on National Dental PBRN stationery and will inform the dentists that they will be receiving an email with a link to the electronic version of the questionnaire that will need to be completed. Dentists will be informed that ideally the questionnaire must be completed in one-sitting, although they will be given an option to save and complete the questionnaire at a later time and that it would take up to 30 minutes to complete.

6.3 Study Activities

Eligible dentists will be assigned to one of five waves. Waves 1 through 4 constitute activities that occur from Baseline through Day 98 (+ 14 days). Thus dentists in wave 1 will receive the postal invitation and subsequent email first; after 2 weeks dentists in the second wave will receive the postal invitation and subsequent email; after 2 weeks dentists in the third wave will receive the postal invitation and subsequent email and finally dentists in the fourth wave will receive the postal invitation and subsequent email. Dentists in Waves 1 through 4 will have an opportunity to complete an electronic or paper version of the questionnaire in order to increase participation rates.

The procedures for eliciting responses to the questionnaire for waves 1 through 4 are outlined below:

Baseline (Day 0)

- All eligible dentists (i.e., N = approximately 2,000) will first receive a study invitation postal mailing from the CC team and/or study staff inviting them to participate in the study. The invitation will indicate that the dentist will receive an email with a link to the electronic version of the questionnaire soon.

Time (T) Day 14 (+ 14)

- Approximately two weeks after the study invitation postal mailing, the dentist will receive the email with a link to the electronic version of the questionnaire.
- At the time the initial email is sent a link will be provided to eligible dentists to give them an opportunity to request a paper copy of the questionnaire.
- Dentists will be given approximately two weeks to complete the questionnaire.

T Day 28 (+ 14)

- If a response from the dentist is not received within two weeks of the initial email, a first reminder email will be sent and the dentist will be given an additional two weeks to complete it.

T Day 42 (+ 14)

- If a response from the dentist is not received within two weeks of the first reminder email, a second reminder email will be sent and the dentist will be given an additional two weeks to complete it.

T Day 56 (+ 14)

- If a response is still not received within two weeks of the second reminder email, the dentist will be sent a third reminder email and a paper copy of the questionnaire by postal mail along with a letter which will include the web address where they can access the online survey. The letter will strongly encourage the dentists to complete the questionnaire online.

T Day 70 (+ 14)

- If a response is not received within two weeks after the third reminder email and postal questionnaire, a second postal questionnaire only attempt will be made with a letter as indicated previously strongly encouraging the dentists to complete the questionnaire online.
- If a response is not received within two weeks these dentists will be considered non-respondents and will be followed up by the RCs.

T Day 84 (+ 14)

- A list of non-respondents will be provided by the CC for the RCs to follow-up with the dentist to ensure that the email and postal invitations were received by the dentist, instead of having been received by office staff or other personnel. The RCs will provide feedback to the CC on the status of the dentists considered non-respondents i.e., the dentist may either complete the questionnaire or may provide a reason for not participating.

T Day 98 (+ 14)

- If no feedback is received or the dentists do not complete the electronic or paper version of the questionnaire after 14 weeks (+ 2 weeks) from the initial study invitation postal mailing, it is assumed they are not interested in the study.

6.4 Other Follow-Up – Waves 1 through 4

- Dentists who choose to save and continue the questionnaire at a later time or request a paper copy of the questionnaire will be sent reminder emails.
- The reminder emails will be sent as noted above but for a maximum of two reminder emails only.
- If after two attempts the dentist does not respond they will not receive additional paper copies of the questionnaire but will be contacted by RCs to encourage completion of the survey.

6.5 Wave 5

Since dentists will be pre-selected prior to the study launch a fifth wave will be added to enroll additional eligible practitioners who join the network after the study is open. These practitioners will not follow the protocol as described for waves 1 through 4; they will receive one initial email invitation with a link to the electronic version of the questionnaire and one reminder email to complete the survey. The practitioners will only be able to complete the survey online, no paper surveys will be provided. The study activities for Wave 5 are as follows:

Baseline (Day 0)

- All eligible dentists will receive an email with a link to the electronic version of the questionnaire. Dentists will be given approximately two weeks to complete the questionnaire.

T Day 14 (+ 14)

- If a response from the dentist is not received within two weeks of the initial email, a first reminder email will be sent and the dentist will be given an additional two weeks to complete it.

T Day 28 (+ 14)

- If a response is not received within two weeks these dentists will be considered non-respondents and will be closed out of the survey.

Dentists in wave 5 who choose to save and continue the questionnaire at a later time will be sent one reminder email. The reminder emails will be sent as noted above. If after one attempt the dentist does not respond they will be closed out of the survey by the CC.

See Appendix C for a description of the study timeline for waves 1 through 5.

6.6 Alternative Methods to Complete the Questionnaire

If an Annual Regional Meeting is held after invitation letters are sent and before the practitioner has completed the questionnaire, the practitioner will be given the option of completing the questionnaire at the meeting. In these cases, the RC will provide a copy of the questionnaire to the eligible dentists at the meeting for completion. If completed at the meeting the RC will send the questionnaire to the CC for data entry until which time the practitioner will receive reminders. If not completed at the meeting the practitioner will also receive reminders as noted above.

7 STUDY PROCEDURES

7.1 Questionnaire Administration

Section 6 details the procedures on questionnaire administration. A copy of the questionnaire can be found in Appendix B.

The purpose of the questionnaire is to collect detailed information on the dentists' use of isolation techniques when performing RCTs. The questionnaire is also designed to collect information to better understand factors that may be associated with use or non-use of rubber dams when performing RCTs, including dentists' knowledge, attitude, perceived skills, general root canal practices, and practice-level characteristics (e.g., type of practice, geographic location).

The questionnaire will be administered to all eligible dentists in the National Dental PBRN by the CC (see section 6 for details on the schedule and the format for administration of the questionnaire).

The questionnaire has not been previously validated. Items and constructs included are guided by prominent theories in behavioral science, as well as pertinent models in implementation research.

The questionnaire includes items to collect the data and assess the constructs specified in subsection 3.2. Note that some information will be collected from the Enrollment Questionnaire (e.g., demographics and practice characteristics) and linked to participants' responses to the proposed study questionnaire.

8 ASSESSMENT OF SAFETY

8.1 Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

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.

8.1.2 Serious Adverse Events

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death;
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- Results in inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability or incapacity;
- Results in a congenital anomaly or birth defect.

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

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.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and 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 1 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

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231
- International: 919-595-6486

9 STUDY OVERSIGHT

The Grant Principal Investigator (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 promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

10 CLINICAL SITE MONITORING

Clinical site monitoring will not occur for this study since the CC is responsible for launching the survey and collecting data received as part of the survey. Quality assurance (QA)/Quality Control (QC) activities associated with data collection and processing will be outlined in the data management plan (DMP). The CC will ensure that the quality and integrity of study data and data collection are maintained, as is detailed in the DMP. The RCs will be responsible for following up with eligible dentists who are considered non-respondents (see Section 6) to encourage study participation.

11 STATISTICAL CONSIDERATIONS

11.1 Study Hypotheses

Hypothesis 1: There is a gap between recommended use of rubber dams when performing RCTs (100%) and actual self-reported use of rubber dams when performing RCTs ($\leq 100\%$).

Hypothesis 2: Specific dentist- and practice-level characteristics are associated with use of rubber dams when performing RCTs.

11.2 Sample Size Considerations

Based on a recent review of dentists enrolled in the National Dental PBRN, we anticipate approximately 2,000 dentists will be eligible to participate in this study. Based on previous PBRN survey studies, we anticipate a response rate of approximately 60-70%. Note that although we could likely achieve the exploratory study objectives through a smaller sample size, we have decided to survey the full sample of eligible dentists as an opportunity to engage network members in this new funding cycle. Because this study is primarily exploratory in nature, sample size calculations are not applicable.

Sample size for test-retest needs to be sufficient to enable an investigator to distinguish unacceptably low kappas from those of acceptable value. In analyses below (page 35), we specify an unacceptably low kappa value as 0.2; this is a value which would bring question the reliability and/or validity of the data, perhaps because of the wording of the question. Consequently, primary analyses will exclude these data items. A kappa of 0.6 or greater is considered acceptable. In determining an appropriate sample size for reliability analysis (test-retest), we focused on distinguishing a kappa of 0.6 from 0.2. Furthermore, we focused on questions (items) for which one of five categories is to be selected [#23 to #55] as they comprise over half of the survey instrument, and kappas for multi-categories are typically lower than for dichotomous. A sample size of 40 will provide the ability to distinguish a moderately high kappa, e.g., 0.6, from an unacceptably low kappa of 0.2, with over 80% power for the 5 category questions for a variety of responses: uniform, bimodal, etc. Furthermore, from simulation analysis examining the precision of kappa estimates, with a sample size of 40, for 5 category questions, a kappa of 0.6 can be estimated, with a 95% confidence interval of 0.44 to 0.78; a kappa of 0.2 can be estimated with a 95% confidence interval of 0.01 to 0.39. These simulations assumed a uniform response across the 5 categories, but as with testing, were relatively invariant to the assumed distribution of responses, namely, uniform, bimodal, central peak or skewed. As can be seen in the width of the confidence intervals, a sample size of 40 should be sufficient to assess the reliability of the instrument.

11.3 Final Analysis Plan

Basic descriptive statistics will be used to characterize the sample in terms of dentist (e.g., age, gender, race/ethnicity) and practice variables (e.g., type of practice, location). Descriptive statistics will also be used to characterize the following: Frequency of RCTs performed and referred per month (by tooth involved [anterior, premolar, and molar] and whether or not the tooth has gingival/subgingival caries); frequency of isolation techniques utilized when performing RCTs (e.g., cotton rolls or gauze, Isolite™, rubber dam); preferred root canal techniques (endodontic instrumentation, obturation); preferred canal irrigation; preferred root canal materials (sealers, canal fill); and information, attitude/motivation and perceived skills constructs detailed in section 3.

The primary outcome variable is use of rubber dams during RCT. As standard of care is use 100%, one set of analyses will use this definition, or use that may be considered virtually all the time (e.g., $\geq 95\%$). The outcome will also be assessed as a continuous variable. The distribution of the reported percent will be tested for normality; if not normally distributed, nonparametric test or in transformation will be used. These are both consistent/appropriate for hypothesis #1, but will provide different information; both of interest.

As stated in section 3, the analyses for the primary outcome will be performed separately (stratified) for type of tooth involved (anterior, premolar and molar) and whether or not tooth has gingival/subgingival caries. It is anticipated that RCT on anterior teeth will be a smaller number than on molars, with premolars being intermediate. There is no *a priori* expectation for differences in use of rubber dams for tooth type.

Hypothesis #1, continuous: Test whether or not mean percent of RCT for which rubber dams are used is less than 100%. Bivariate analysis will use normalized Z-score or nonparametric equivalent. In addition, 95% confidence intervals will be constructed to obtain the 'range' of percent of RCT for which rubber dams are used, overall and by tooth type and whether or not tooth has gingival/subgingival caries.

Hypothesis #1, dichotomous: Test whether or not proportion of dentists who use rubber dams when performing RCT is less than 100%. Bivariate analysis will use chi-squared test (Fisher's exact test). In addition, 95% confidence intervals will be constructed to obtain the 'range' of proportions of dentists who use rubber dams all, or virtually all of the time, overall and by tooth type and whether or not tooth has gingival/subgingival caries.

Overview of analytic approach (details in following tables)

All analyses will be performed using SAS 9.3.

The relation of each variable of interest (secondary 'outcomes' described in section 3) with the primary outcome (use of rubber dams) will be assessed individually. For continuous outcome, ANOVA or nonparametric alternative will be used; for dichotomous outcome, either chi-square or ANOVA will be used.

Analysis will start with region, dentist and practice characteristics, with goal of reducing number of variables and ascertaining if appropriate to use as continuous or categorical, e.g., age, year graduated, and how categorized, e.g., may combine race-ethnicity as Non-Hispanic white or not, depends on numbers (cell size) and associations with outcome.

Next, the following variables will be assessed with the primary outcome measure to determine the association of these variables with use or non-use of rubber dams when performing RCTs: Frequency of RCTs performed per month; frequency of preferred techniques, irrigation, and materials. Next, the information, attitude/motivation, and perceived skills constructs will each be independently assessed with the primary outcome. For these latter three 'qualitative' constructs, the primary purpose is to verify that the individual components are associated with the outcome in at least a similar fashion, specifically, that the components are not associated in opposite directions. It is anticipated that the components will be highly correlated, associated with outcome in same direction. The verification that each of the components of a construct contribute to the construct will be performed using Spearman rank correlations. It is anticipated that the components of a construct will be highly correlated with other components of the construct, e.g., $r > 0.5$, and that they will have correlations with the outcome in the same direction. A correlation matrix of the components of a construct will be built. Though we will not require a high correlation at this stage in the analysis, an inverse correlation or very weak correlation (e.g., $r < 0.1$) would be evidence that the component did not contribute to the construct. If this occurs, the component would not be included in the final composite construct score. Furthermore, the correlation of each component with the outcome, proportion of RCT for which rubber dams are used, will be calculated. It is posited that each component will be correlated with the outcome in a similar fashion, namely, direction. There is no a priori requirement of each component having a high correlation with the outcome (objective 2 is ascertaining whether or not these constructs are associated with the outcome). To be part of the same construct, the components should have similar associations with the outcome, at a minimum in terms of direction. If a putative component is correlated with the outcome in the opposite direction from the other components, that component would not be used in creating the composite construct score. After the above verifications have been performed, a composite construct score will be computed by summing component scores, which will be coded in 1-unit intervals (either -2 to +2, or 1 to 5), with higher numbers being associated with more rubber dam use.

To further assess the association between the constructs and the outcome variable, general linear models will be used when the primary outcome variable is continuous;

emphasis will be on ANOVA. This analytic technique will 1) allow estimation of percent of variance explained by proposed constructs; 2) allow assessment of whether or not they have independent associations with the outcome; and 3) be relatively robust to moderate departure from normality, especially if the sample distribution is nearly symmetric, while other techniques, such as factor analysis, are much more sensitive to violation of the distributional assumption.

Variable/Construct	Questionnaire items to address it	Predicted structure of the construct	Statistical analyses - bivariate	Statistical analyses – adjusted (multivariable)
Variables				
Instrumentation	Q#2	No a priori expectation	ANOVA	GLM/ANOVA
Irrigation	Q#3	No a priori expectation	ANOVA	GLM/ANOVA
Sealers	Q#4	No a priori expectation	ANOVA	GLM/ANOVA
Obturation techniques/materials	Q#5	No a priori expectation	ANOVA	GLM/ANOVA
Canal fill materials	Q#6	No a priori expectation	ANOVA	GLM/ANOVA
	The analyses above will focus on how best to treat/categorize the variables, first assessment of association with use of rubber dams. Will look at overall, then stratified by type/location of tooth. Will also assess association with practice/dentist characteristics.			
Variables	Separate models will be run for type/location of involved tooth (stratified). Depending on frequency/distribution of use of other techniques, will treat as categorical [ANOVA] or continuous [correlation].			
Frequency/use of other isolation techniques	Q#11,12: Anterior	inverse	ANOVA/correlation	GLM/ANOVA
	Q#14,15: Premolar	inverse	ANOVA/correlation	GLM/ANOVA
	Q#17,18: Molar	inverse	ANOVA/correlation	GLM/ANOVA
	Q#20,21: Caries	No a priori expectation	ANOVA/correlation	GLM/ANOVA
	The association of the variables above (Q#2-22) with practice/dentist characteristic will also be assessed (correlation, chi-square, ANOVA). These variables will be added to the practice/dentist variables assessed first to ascertain independent associations.			
Constructs				
Information	Q#23-34 (some specific for anterior, premolar, molar – will be used for those models)	Each question, then sum: positive	correlation	GLM/ANOVA
Motivation/attitude	Q#35-43	Each question, then sum:	correlation	GLM/ANOVA

		positive		
Skills	Q#44-55	Each question, then sum: positive	correlation	GLM/ANOVA
	After each construct has been built, then association of each built construct with outcome will be assessed (bivariate). The interrelations of the constructs will be assessed using correlation matrix. It is anticipated that they will be correlated, though weak or moderate ($r < 0.5$), not strong; a strong correlation would indicate the same construct. The constructs will be added to the model already built, one at a time. This will be done at least 3 ways, varying which construct is added first: information, motivation/attitude, behavior. For example, add behavior construct first, ascertain what it adds to the model (percent of variation). Next add another construct, say motivation/attitude; ascertain what that construct adds in addition to the behavior construct already included. If they are separate constructs, they will have independent associations with rubber dam use, regardless of the order to which they are added to the model. However, by building models sequentially, we can, to some extent, evaluate pathways..			

For dentists who perform RCT on all types/location of teeth (anterior, premolar, molar), an overall model will be built using procedure above. The outcome will be a weighted average (anterior, premolar, molar) of percent of RCT for which dentist used rubber dams. Additional analyses will look at characteristics of dentists who perform RCT on anterior, premolars, and molars compared to dentists who only perform RCT on only 1 or 2 locations, probably molars.

Logistic regression will be used when outcome is dichotomous, which is also robust to distribution of independent variables. The procedure will be analogous to that described above for GLM. Care will be taken in any per unit interpretation of coefficients (odd ratios) due to the use of Likert scales; the intervals in the item scores are not equal. In this sense, the item scores are fundamentally different from normally-distributed scores, from an interpretability point of view.

Test/Re-test Analysis

The primary analytic plan is to assess each item individually; the median and inter-quartile range of kappas for each item will be assessed. Though they will be assessed individually, they will also be assessed in groups. The items (questions) will be grouped two ways: based on tooth location and on construct. Items for which the median kappa is less than 0.2 will be excluded from primary overall analysis.

Missing Data

Once data collection is complete, we will examine both *unit* non-response rates and *item* non-response rates. Unit non-response rates are based on the number of participants who do not respond to the request to be surveyed (i.e., who do not complete the electronic or paper version of the questionnaire after 12-weeks from the

initial study invitation postal mailing), and commonly result from an inability to contact the participant or from the individual's decision not to participate in the study.^{22,23} We will examine differences between survey participants and non-participants with respect to basic demographic information and practice-characteristics based on information collected from the Enrollment Questionnaire. If any statistically significant differences between participants and non-participants are observed, they will be noted as a limitation of our study findings in terms of potential generalizability to the broader population, as appropriate.

We will also examine item non-response rates. Item non-response rates occur when a given unit (i.e., person) does not provide a substantive response to a particular question, and often result from the participants' inability or unwillingness to provide such information.^{22,23} To assess item non-response rate, we will assess the frequency with which each item in the survey is left blank and each item where the participant selected the response option "I prefer not to answer" (as available). Differences between those who provided a response to the item vs. those that did not will be examined with respect to basic demographic and practice-level characteristics on items with greater than 20% missing data.^{22, 23} Appropriate statistical techniques (e.g., exclusion; imputation)²⁴ will be used to adjust for any potential bias in response rates, as appropriate.

12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Source data/documents will be maintained by the CC for this study. The CC will use a survey management system (SMS) to program the electronic questionnaire. Participants are sent an email invitation with a direct link to the electronic questionnaire. After a participant submits the electronic questionnaire, data will be available in the SMS. Participants responding via paper questionnaire will return their completed questionnaires to the CC via a pre-paid, pre-addressed mailing envelope and data entry staff will enter data from the paper questionnaires into the SMS. The system will identify the mode (electronic or paper) of data entry for reporting and tracking purposes.

Only study personnel i.e., the SPI, NND and CC staff will have access to these data elements. All research computers and associated study documents will be password-protected. Data files will be kept in a secure, locked file in the SPI's office for approximately three years after the study has been completed, in accordance with regulations set forth by the IRB. A copy will also be stored on a password-protected UAB network computer only accessible to the NND. As outlined by IRB regulations, data will be destroyed in an appropriate and safe way approximately three years (e.g., files will be securely deleted from computers) after the study has been classified as closed.

13 QUALITY CONTROL AND QUALITY ASSURANCE

For the QA/QC activities associated with data collection and processing, the CC will develop a DMP in which the specific data QA/QC procedures will be provided. The procedures will include the development of automatic data quality checks in the SMS and the processes related to the data manual review, discrepancy management, delinquent data handling, data updates, data verification and data audits.

The SPI will work closely with the CC to ensure that the electronic and paper questionnaires are being collected appropriately and confidentially. Conference calls will be held approximately every two weeks during the data collection phase to monitor progress, manage study documentation and procedures, and troubleshoot any problems that may arise. Calls will also be held with the RCs to review contact information of eligible dentists, discuss recruitment issues and enrollment progress, manage study documentation and procedures, and troubleshoot any problems related to enrollment that may arise.

Responses from paper questionnaires will be entered manually by the data entry staff at the CC into the SMS for subsequent data analysis. A one hundred percent review of data entered will be completed, comparing to the original paper questionnaire copies for accuracy. If errors are found, they will be remediated.

14 ETHICS/PROTECTION OF HUMAN SUBJECTS

14.1 Ethical Standard

The GPI and SPI 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.

14.2 Institutional Review Board

The protocol, recruitment materials and all participant materials will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before any participant is enrolled. 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

A waiver of documentation of signed informed consent for participants who complete the electronic or paper questionnaire will be requested. Consistent with regulations outlined by the UAB IRB, information about the study will be provided to eligible dentists in an initial study invitation letter as well as in the electronic or paper questionnaire prior to the start of the survey questions. Completion of the questionnaire will provide tacit consent.

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

Minors will not be enrolled in this study. Dentists of any gender or racial/ethnic group may participate if they meet eligibility criteria.

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., NND, SPI, CC staff) will have access to research study documents. Participants' pre-assigned identification numbers (i.e., practitioner IDs (PID) assigned by the National Dental PBRN) will be used to maintain study records and organize data files. A file linking participants' names with their unique identification number will be kept in a password-protected file on the CC's computer and will be destroyed after the study analysis is completed in accordance with regulations set forth by the IRB.

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 procedures as outlined in the DMP.

Access to study data will be provided to study team members, including the SPI, RCs and CC staff.

15.1 Data Management Responsibilities

The SPI will work closely with the CC to ensure that the electronic and paper questionnaires are being collected appropriately and confidentiality is being maintained according to the protocol specified procedures.

Staff at the CC will develop and maintain a SMS based on the study questionnaire. The DMP will include details on the SMS and procedures that would be followed to launch and monitor the study. The data reported in the network's Practitioner Database will be reviewed by the CC staff to identify eligible dentists for this study. The study questionnaire will then be completed by those that are eligible and are willing to participate in this study. All data reported in the SMS will be checked by the CC staff for completeness and consistency. Any data issues identified will be communicated with the study team as appropriate according to the procedures specified in the DMP.

When paper questionnaires are used, the CC staff will be responsible for reviewing the forms to ensure the data are completed clearly and legibly, and entering the forms into the SMS. An audit will be performed on the data that are manually entered by the CC staff. The RCs will assist the CC staff on any data issues identified during the data collection process. The CC will maintain all paper forms, a data entry log, and an issue tracking log.

15.2 Data Capture Methods

All eligible network dentists will be invited to participate in this study and can use either the electronic or paper version of the questionnaire.

The SMS will ensure that all required data are collected per protocol requirements, and the data fields in the system are checked for completeness and consistency so that data entered into the web system or paper forms can be validated and data errors be corrected. Edit checks will be programmed into the web survey to correct data issues in real time. Reports or tools will be developed to help monitor the data activities. The reports with the summary of the data completion by the participants will be made available on the network web site if requested.

The paper forms will be sent to the CC staff for data entry and maintained at the CC securely. The CC staff will ensure that all paper forms received are entered in the SMS in a timely manner and the data entered are accurate as they are captured on the paper forms.

15.3 Types of Data

Data consist of participants' responses to the electronic or paper questionnaire.

15.4 Schedule and Content of Reports

Ongoing reports to monitor enrollment will be produced approximately every 2 weeks for study team and NIDCR review. The contents of the reports will include the summary of data collected in the questionnaire and can be developed in separate sections by key characteristics or regions.

Final data analysis reports that address objectives of the study will be produced for study team and NIDCR review by the CC Statistician. The content of these reports will be determined by the CC Statistician, in consultation with the SPI, and other study team members and defined in the Statistical Analysis Plan.

The procedure for locking the database prior to final analysis will be detailed in Section N of the study Data Management Plan, in accordance with the CCs Standard Operating Procedure (SOP) *DSD-001: Development of a Data Management Plan* (see Appendix D) and *SOP DSD-405: Data Lock*. Briefly, the SMS data will be locked and final SAS datasets will be generated at the end of the study. Prior to locking the database, the Clinical Data Manager (CDM) or designee will ensure all data is complete and clean. Then, the CDM will obtain approval from the SPI and Project Manager to proceed with the data lock. The CDM will then direct the System Development Manager to lock the database. The date and time of database lock will be documented. All team members will receive written notification from the CDM or designee when the database lock is complete.

No masking or coding is anticipated for this study.

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 NIH.

As outlined by IRB regulations, data will be destroyed in an appropriate and safe way after approximately three years (e.g., and files will be securely deleted from computers).

15.6 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol or Good Clinical Practice (GCP) principles. The noncompliance may be on the part of the subject, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

All deviations from the protocol must be maintained in a log and promptly reported to NIDCR and the local IRB, according to their requirements.

16 PUBLICATION 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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APPENDICES

Appendix A: Summary of Proposed Phase II Study

Appendix B: Isolation Techniques Questionnaire

Appendix C: Study Timeline

Appendix D: Summary of Data Management Plan

APPENDIX A: SUMMARY OF PROPOSED PHASE II STUDY

The proposed Phase II study consists of developing and administering a set of clinical vignettes with a sample of participants who complete the isolation techniques questionnaire in Phase I. Pursuit of the proposed Phase II study is contingent upon outcomes of Phase I and discussion with NIDCR Program Officers.

The SPI will work with Dr. Michael Robinson, PhD, Professor, University of Florida, to develop and pilot test a set of clinical vignettes to better understand which specific factors influence dentists' decision to use or not use a rubber dam when performing RCT. Coupled with data collected from Phase I, this information will allow us to better understand what factors are associated with rubber dam use and non-use, and help identify strategies that can be used to effectively and efficiently change dentists' practice behavior.

APPENDIX B: ISOLATION TECHNIQUES QUESTIONNAIRE

SECTION 1: PRACTICE CHARACTERISTICS

This section asks if any changes have occurred to your dental practice since you answered the National Dental PBRN Enrollment Questionnaire.

1. When you completed the National Dental PBRN Enrollment Questionnaire you had indicated you were a general dentist. Are you still a general dentist?
 - a. Yes [SKIP TO Q3]
 - b. No

2. Which **one** of the following best describes your current dental practice?
 - a. Endodontist [SKIP TO END OF SURVEY]
 - b. Pediatric Dentist [SKIP TO END OF SURVEY]
 - c. Periodontist [SKIP TO END OF SURVEY]
 - d. Prosthodontist [SKIP TO END OF SURVEY]
 - e. Oral/Maxillofacial Surgeon [SKIP TO END OF SURVEY]
 - f. Orthodontist [SKIP TO END OF SURVEY]
 - g. Other, please specify: _____ [SKIP TO Q3]

3. Since you answered the National Dental PBRN Enrollment Questionnaire, have you changed your type of practice (that is: Owner of a private practice; Associate or employee of a private practice; HealthPartners Dental Group; Permanente Dental Associates; Other managed care or preferred provider organization; Public health practice; Federal government facility; Dental school or academic dental institution)?
 - a. Yes
 - b. No [SKIP TO Q5]

4. Which **one** of the following best characterizes the type of practice in which you currently work?
 - a. Owner of a private practice
 - b. Associate or employee of a private practice
 - c. HealthPartners Dental Group
 - d. Permanente Dental Associates
 - e. Other managed care or preferred provider organization
 - f. Public health practice, community health center, or publicly-funded clinic (but not a federal facility)
 - g. Federal government facility (e.g., VA, Department of Defense, Public Health Service)
 - h. Dental school, academic dental institution, or facility staffed by the dental school

SECTION 2: GENERAL ROOT CANAL PRACTICES

This section asks questions about your general root canal practices. By “root canals”, we mean the number of teeth treated with root canal fillings, rather than the number of canals treated.

5. Do you personally perform **one or more** root canals per month?
 - a. Yes
 - b. No [SKIP TO END OF SURVEY]

6. Which of the following do you use for endodontic instrumentation? Please select all that apply.
 - a. Standard nickel-titanium (NiTi) hand K files
 - b. Engine-driven nickel-titanium (NiTi)
 - c. Stainless steel hand K files
 - d. Rotary endodontic instruments
 - e. Some other endodontic instrumentation, please describe:

7. Which of the following do you use for canal irrigation? Please select all that apply.
 - a. Normal saline
 - b. Sodium hypochlorite
 - c. Local anesthetic solution
 - d. Hydrogen peroxide
 - e. Chlorhexidine
 - f. Some other canal irrigation, please describe: _____

8. Which of the following sealers do you use during root canals? Please select all that apply.
 - a. Zinc oxide-eugenol (ZOE)
 - b. Epoxy resin based
 - c. Calcium hydroxide
 - d. Glass ionomer
 - e. Some other sealer, please describe: _____

9. Which of the following obturation techniques do you use? Please select all that apply.
 - a. Lateral condensation or vertical compaction
 - b. Continuous wave technique (vertical compaction of core material and sealer in apical portion of root canal using commercially-available heating devices and then back-filling the remaining portion of the root canal with thermoplasticized core material using injection devices)
 - c. Thermoplasticized injection technique (e.g., injection of material at a high temperature)

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- d. Carrier-based techniques (gutta percha is coated on a carrier before heating and/or delivery to the canal)
 - e. Thermomechanical compaction technique using rotary instruments
 - f. Use of paste fillers
 - g. Some other obturation technique, please describe:

10. Which of the following canal fill materials do you use? Please select all that apply.

- a. Gutta percha
- b. Resin root filling materials (Resilon®)
- c. Resin-coated gutta percha cones
- d. Endodontic paste fillers
- e. Apical barrier material (e.g., mineral trioxide aggregate)
- f. Some other canal fill material, please describe:

SECTION 3: ANTERIOR TOOTH ROOT CANAL TREATMENT

This section concerns root canal treatment that you perform on anterior teeth.

11. In an average month, how many anterior tooth root canals do **you** personally perform? If you do not perform anterior tooth root canals, please enter '0'.

- a. [Enter number]

[IF '0', SKIP TO Q13]

12. When **you** personally perform anterior tooth root canals, what percentage of the time do you use the following isolation techniques?

- a. Rubber dam: _____%
- b. Cotton roll or gauze: _____%
- c. Isolite™: _____%
- d. Some other type of isolation technique: _____% Please specify:

- e. Some other type of isolation technique: _____% Please specify:

- f. No isolation technique is used: _____%

13. In an average month, how many anterior tooth root canals do you **refer** to a different dentist or endodontist? If you do not refer any anterior tooth root canals, please enter '0'.

- a. [Enter number]

SECTION 4: PREMOLAR TOOTH ROOT CANAL TREATMENT

This section concerns root canal treatment that you perform on premolar teeth.

14. In an average month, how many premolar tooth root canals do **you** personally perform? If you do not perform premolar tooth root canals, please enter '0'.
- [Enter number]

[IF '0', SKIP TO Q16]

15. When **you** personally perform premolar tooth root canals, what percentage of the time do you use the following isolation techniques?
- Rubber dam: _____%
 - Cotton roll or gauze: _____%
 - Isolite™: _____%
 - Some other type of isolation technique: _____% Please specify:

 - Some other type of isolation technique: _____% Please specify:

 - No isolation technique is used: _____%

16. In an average month, how many premolar tooth root canals do you **refer** to a different dentist or endodontist? If you do not refer any premolar tooth root canals, please enter '0'.
- [Enter number]

SECTION 5: MOLAR TOOTH ROOT CANAL TREATMENT

This section concerns root canal treatment that you perform on molar teeth.

17. In an average month, how many molar tooth root canals do **you** personally perform? If you do not perform molar tooth root canals, please enter '0'.
- [Enter number]

[IF '0', SKIP TO Q19]

18. When **you** personally perform molar tooth root canals, what percentage of the time do you use the following isolation techniques?
- Rubber dam: _____%
 - Cotton roll or gauze: _____%
 - Isolite™: _____%
 - Some other type of isolation technique: _____% Please specify:

e. Some other type of isolation technique: _____% Please specify:

f. _____ No isolation technique is used: _____%

19. In an average month, how many molar tooth root canals do you **refer** to a different dentist or endodontist? If you do not refer any molar tooth root canals, please enter '0'.

a. [Enter number]

SECTION 6: ROOT CANAL TREATMENT ON TEETH WITH GINGIVAL/SUBGINGIVAL CARIES

This section concerns root canal treatment that you perform on teeth with gingival/subgingival caries.

20. In an average month, how many root canals do **you** personally perform on teeth with gingival/subgingival caries? If you do not perform root canals on these teeth, please enter '0'.

a. [Enter number]

[IF '0' SKIP TO Q22]

21. When **you** personally perform root canals on teeth with gingival/subgingival caries, what percentage of the time do you use the following isolation techniques?

a. Rubber dam: _____%

b. Cotton roll or gauze: _____%

c. Isolite™: _____%

d. Some other type of isolation technique: _____% Please specify:

e. _____ Some other type of isolation technique: _____% Please specify:

f. _____ No isolation technique is used: _____%

22. In an average month, how many root canals on teeth with gingival/subgingival caries do you **refer** to a different dentist or endodontist? If you do not refer any of these root canals, please enter '0'.

a. [Enter number]

SECTION 7: ATTITUDES TOWARD ROOT CANAL PRACTICES AND TREATMENT

Please indicate the extent to which you disagree or agree with the following statements. There are no right or wrong answers to these questions; we are simply interested in your thoughts about the statements below.

23. I received sufficient knowledge and training in dental school on how to effectively place a rubber dam prior to performing a root canal.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
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24. Cotton rolls or gauze are just as effective as the rubber dam when root canals are done on **anterior** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
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25. Cotton rolls or gauze are just as effective as the rubber dam when root canals are done on **premolar** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
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26. Cotton rolls or gauze are just as effective as the rubber dam when root canals are done on **molar** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

27. Isolite™ is just as effective as the rubber dam when root canals are done on **anterior** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
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28. Isolite™ is just as effective as the rubber dam when root canals are done on **premolar** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

29. Isolite™ is just as effective as the rubber dam when root canals are done on **molar** teeth.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

30. Using a rubber dam during root canals reduces the likelihood of infection for patients.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

31. Using a rubber dam during root canals decreases the likelihood of infection for practitioners and office staff.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

32. Using a rubber dam when performing root canals reduces the potential for swallowed or aspirated dental items.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

33. Using rubber dams when performing root canals improves treatment effectiveness.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

34. Rubber dams control moisture very well during root canals.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

35. It's very important to use a rubber dam every time a root canal is performed.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

36. Rubber dams tear frequently.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

37. Rubber dams make it easier to perform root canals.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

38. Most dentists I know use rubber dams when performing root canals.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

39. Placing a rubber dam before performing a root canal is time-consuming.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

40. Clamp placement requires the use of additional anesthesia around the gumline when rubber dams are used to perform root canals.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

41. Using rubber dams to perform root canals is inconvenient.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

42. Patients are uncomfortable wearing a rubber dam during root canals.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

43. Maintaining an adequate supply of rubber dams in one's practice is difficult.

Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
-------------------	----------	----------------------------	-------	----------------

SECTION 8: SPECIFIC QUESTIONS ABOUT ROOT CANAL PRACTICES

The following questions ask about engaging in a variety of particular tasks or behaviors.

How hard or easy is it for you to

44. ...place a rubber dam to perform a root canal?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

45. ...place a rubber dam on an **anterior** tooth to perform a root canal?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

46. ...place a rubber dam on a **premolar** tooth to perform a root canal?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

47. ...place a rubber dam on a **molar** tooth to perform a root canal?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

48. ...fit a clamp that is too big, too small, or of awkward size for the tooth?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

49. ...place a rubber dam when you have limited access and visibility of the isolated operating area?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	-----------------------	------	-----------

50. ...place a rubber dam when the patient doesn't have the ability to open his/her mouth very wide?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

51. ...explain to a patient the importance of using a rubber dam to perform a root canal?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

52. ...communicate with the patient (as needed) during a root canal when a rubber dam is being used?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

53. ...use a rubber dam to perform a root canal with a patient who is claustrophobic, talkative, a gagger, and/or has a breathing problem (e.g., COPD)?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

54. ...get assistance from auxiliary staff to place a rubber dam when needed?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

55. ...use a rubber dam to perform a root canal when you have competing demands in your clinic (e.g., other patients are waiting for you to check them after a cleaning)?

Very Hard	Hard	Neither Hard nor Easy	Easy	Very Easy
-----------	------	--------------------------	------	-----------

SECTION 9: ADDITIONAL COMMENTS

56. Is there anything else you think we should know about how you use isolation methods during root canal treatment?

[OPEN FIELDS FOR TEXT ENTRY BY THE RESPONDENT HERE]

SECTION 10: PAYMENT OPTIONS

57. Would you like us to send you or your practice organization \$50.00 as a thank you for completing this survey?

Yes, please send compensation

No [SKIP TO END OF SURVEY]

Thank you for completing this questionnaire.

APPENDIX C: STUDY TIMELINE

Activities	M1	M2	M3	M4	M5	M6	M7	M8	M9
Wave 1 Schematic ¹	→								
Wave 2 Schematic ¹	→								
Wave 3 Schematic ¹	→								
Wave 4 Schematic ¹	→								
Wave 5 Schematic ²	→								
Retest of Questionnaire ³	→								
Receive Final Data from Participants	→								
Data Cleaning Activities ⁴	→								
Database Lock	→								
Dataset Delivery/ Analysis	→								

M= Month; Starts after IRB approval for the protocol is obtained.

1= Each Wave is anticipated to last 16 Weeks. See study schema for activities occurring over each wave.

2= Wave 5 is anticipated to last approximately 4 weeks.

3= Retest will occur over the course of study implementation with 40 randomly selected participants who complete the initial survey.

4=Data cleaning activities include receiving paper forms which could occur after Wave 4 is completed, following up with participants for any discrepancies and QA of paper questionnaire data. The study will be considered closed to new data after a month following Wave 4 activities.

APPENDIX D: SUMMARY OF DATA MANAGEMENT PLAN

The Isolation Techniques Study has Standard Operating Procedures (SOPs) which require the development of a DMP for each project for which the CC provides Data Management services. The CC SOPs require that the DMP be developed according to a standard template containing the following sections, where applicable:

- Section A: Protocol Summary, Estimated Time to Complete Enrollment, Study Objectives
- Section B: Definitions And Acronyms
- Section C: Roles/Responsibilities Of Key Organizations
- Section D: Case Report Forms (CRFs)
 - D.1: CRF Development Or Review
 - D.2: CRF Completion Instructions
 - D.3: CRF/ CRF Completion Instructions Revisions
- Section E: Database/Systems Development
 - E.1: Clinical Database
 - E.2: Safety Database
 - E.3: Randomization Database
 - E.4: Imaging System
 - E.5: Electronic Data Loading System
 - E.6: Other Database Or DM System
 - E.7: Database Security/Back Up
- Section F: Training
 - F.1: Paper CRF Completion
 - F.2: Clinical Database/Data Entry
 - F.3: Other Database Or Data Management System
- Section G: Data Processing Of CRF
 - G.1: CRF Receipt And Tracking
 - G.2: Data Entry
 - G.3: Scanning/Imaging
 - G.4: Filing
 - G.5: Data Processing Of Study-Related Documents (Non-CRF)
- Section H: Receipt And Processing Of Electronic Data
- Section I: Medical Coding
- Section J: Data Quality/Data Cleaning
 - J.1: Edit Check Development
 - J.2: Manual Review Development And Process
 - J.3: Discrepancy Management Process
 - J.3.1: Discrepancy Review And Resolution Codes
 - J.4: Study Assumptions/SECS
 - J.5: Delinquent Data
 - J.6: Data Updates

- J.7: Verification/Approval Functions In OC-RDC
- Section K: Data Reconciliation
 - K.1: Imaging System Reconciliation
 - K.2: Safety Data Reconciliation
 - K.3: Randomization Data Reconciliation
- Section L: Database Audit
- Section M: Reports/Metrics
- Section N: Data Lock
 - N.1: Locking The Data
 - N.2: Unlocking The Data Or Data Updates Post Lock
 - N.3: Data Unblinding
- Section O: Data Transfer
 - O.1: Preparation
 - O.2: Transmission
 - O.3: Schedule
- Section P: Database Close-Out/Archive
- Section Q: Attachments And References