Human Subjects Protocol (HSP)

Form Version: March 8, 2010

- **You are applying** for IRB review of the research described in this form.
- **To avoid delay**, respond to all items in order and include all required approvals and documents.
- **To complete the form**, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck. For more tips, see www.uab.edu/irb/forms.
- **Mail or deliver all materials to AB 470**, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

☐ Convened (Full) IRB *or*

☒ Expedited—See the Expedited Category Review Sheet, and indicate the category(ies) here: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☒7

1. IRB Protocol Title: Infrastructure Update Survey (Dental PBRN Network Chair)

2. Investigator, Contacts, Supervisors

a. Name of Principal Investigator: Gregg H. Gilbert
Degree(s)/Title: DDS, MBA/Professor and Chair BlazerID: ghg
Dept/Div: General Dental Sciences Mailing Address: SDB 109 UAB ZIP: 35294-0007
Phone: 934-5423 Fax: 975-0603 E-mail: ghg@uab.edu

b. Name of Contact Person: Andrea Mathews Title: Program Manager II Phone: 934-2578
E-mail: ahmathews@uab.edu Fax: 996-2172
Mailing Address (if different from that of PI, above):

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and any Co-Investigators or Other Investigators comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed in the protocol and persons obtaining informed consent have completed initial IRB training and will complete continuing IRB training each year;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: _____ **Date:** 10/20/2010

c. List all staff who will be involved with the design, conduct, and reporting of the research, their degree(s) and job title, and any additional qualifications. Include individuals who will be involved in the consent process. *Repeat the table below for each individual.*
Note. For studies involving investigational drugs, include all investigators who will be listed on FDA Form 1572 and attach a copy, if applicable. Send the IRB a copy of Form 1572 anytime you update the form with the FDA.

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Dr. Gregg Gilbert**
Primary UAB Dept.: (Employer if not UAB)	**General Dental Sciences**
Degree(s) / Job Title:	**DDS, MBA/Chair, Professor**
Additional Qualifications pertinent to the study:	____

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Dr. Sonia Makhija**
Primary UAB Dept.: (Employer if not UAB)	**General Dental Sciences**
Degree(s) / Job Title:	DDS, MPH/Assistant Professor
Additional Qualifications pertinent to the study:	____

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Dr. Mark Litaker**
Primary UAB Dept.: (Employer if not UAB)	**General Dental Sciences**
Degree(s) / Job Title:	PhD/Associate Professor
Additional Qualifications pertinent to the study:	____

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Andrea Mathews**
Primary UAB Dept.: (Employer if not UAB)	**General Dental Sciences**
Degree(s) / Job Title:	**BS, RDH/Program Manager II**
Additional Qualifications pertinent to the study:	____

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Sherry Sutphin**
Primary UAB Dept.: (Employer if not UAB)	**General Dental Sciences**
Degree(s) / Job Title:	**BS/Research Assistant**
Additional Qualifications pertinent to the study:	____

Role:	☒Co- *-OR-* ☐Other *-AND/OR-* ☐Consent Process
Full Name:	**Jackie Love**

Primary UAB Dept.: **General Dental Sciences**
(Employer if not UAB)
Degree(s) / Job Title: **CDA/Research Assistant**
Additional Qualifications pertinent to the study: ____

d. Is the principal investigator a student, fellow, or resident? ☐Yes ☒No
If Yes, complete items below and obtain signature of faculty advisor or supervisor:
Supervisor's Name:
Degree(s) / Job Title: ____
Additional Qualifications pertinent to the study: ____
Telephone: ____
E-Mail: ____
Signature: _____

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol:
Dr. Gregg Gilbert will provide full support to this study. He will meet at least once a week with Ms. Andrea Mathews, Ms. Sherry Sutphin and Ms. Jackie Love.

f. Is medical supervision required for this research? ☐Yes ☒No
If Yes, who will provide the supervision?
☐ PI will provide -*OR*- Name:____ Telephone:____
If other than PI, obtain signature of person providing medical supervision:
Signature _____

g. Describe the process that ensures that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions: **All persons assisting with this research were either fully involved in the protocol development and therefore are well informed about the research or have attended training and meetings for their research-related duties.**

3. Funding

Is this study funded? ☒Yes ☐No
If No, specify that costs of the study will be covered by funds from the UAB department or other source named:
If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.
a. Title of Grant or Contract: **Dental PBRN Network Chair**
b. PI of Grant or Contract: **Gregg H. Gilbert, DDS, MBA**
c. Office of Grants & Contracts Administration Link or Tracking Number: **The link is 231770, which is the same as the Dental PBRN Network Chair (U01-DE-16747). This study is a study of the Dental PBRN Network Chair grant, of which Dr. Gregg Gilbert is the Principal Investigator.**

(*or enter "Pending" and provide upon receipt from OGCA*)
d. Sponsor, Funding Route (*check and describe all that apply*):
☒ Gov't Agency or Agencies—Agency name(s): **NIH**
☐ Department of Defense (DoD): Identify DoD component:____

☐ Department of Energy (DOE)
☐ Department of Justice (DOJ)
☐ Department of Education
☐ NIH Coop. Group Trial—Group name:____
☐ Private Nonprofit (e.g., Foundation)—Name:____
☐ Industry, investigator-initiated—Name:____ Describe the funding arrangement:____
Note. Western IRB reviews industry-sponsored protocols unless the investigator initiated the research, or the study qualifies for expedited review or involves gene therapy.
☐ UAB Departmental/Division Funds—Specify:____

4. Conflict of Interest—Human subjects research involving a disclosed financial interest is subject to IRB review following review by the Conflict of Interest Review Board.

The following definitions are used for Item #4:
Immediate family means spouse or a dependent of the employee. *Dependent* is any person, regardless of his or her legal residence or domicile, who receives 50% or more of his or her support from the public official or public employee or his or her spouse or who resided with the public official or public employee for more than 180 days during the reporting period.
Financial Interest Related to the Research means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.
For each investigator and staff member involved in the design, conduct and reporting of the research (see Items 2.a. and 2.c.) answer the questions below: **(Repeat the section below for each individual)**

Name: Dr. Gregg Gilbert

Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

Name: Dr. Sonia Makhija

Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

Name: Dr. Mark Litaker

Do you or your immediate family have any of the following? (check all that apply)

☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

Name: **Andrea Mathews**

Do you or your immediate family have any of the following? (check all that apply)

☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

Name: **Sherry Sutphin**

Do you or your immediate family have any of the following? (check all that apply)

☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

Name: **Jackie Love**

Do you or your immediate family have any of the following? (check all that apply)

☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
- Less than $10,000 in the past year when aggregated for the immediate family.
- Amount will not be affected by the outcome of the research.

☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

5. Locations Involved

a. Describe the facilities available for the conduct of the research. For research on UAB campus, include building names and room numbers: **University of Alabama School of Dentistry and practitioner-investigators' dental practices in the United States and**

Scandinavia (Denmark, Norway, and Sweden) who have participated in at least one Dental PBRN study so far.

b. Indicate all "performance sites" that will provide space, services, facilities, potential or actual participants, or other support for this protocol.

- ☐ The Kirklin Clinic (TKC)
- ☐ University of Alabama Hospital (UAHosp)
- ☐ The Children's Hospital of Alabama (TCHA)
- ☐ Callahan Eye Foundation Hospital (CEFH)
- ☐ UAB Highlands
- ☐ Jefferson County Dept. of Health (JCDH)
- ☐ Birmingham Veterans Affairs Medical Center (BVAMC)
- ☐ General Clinical Research Center (GCRC)—inpatient
- ☐ General Clinical Research Center (GCRC)—outpatient
- ☐ General Clinical Research Center (GCRC) at The Kirklin Clinic (TKC)
- ☒ Other (i.e., Any performance site not listed above, including those covered by subcontracts related to this protocol)—Describe: **School of Dentistry because a small number of DPBRN practitioner-investigators in Alabama are UAB School of Dentistry Faculty who see patients in the school's Faculty Practice and may complete the study questionnaire.**

c. Is this study a clinical trial requiring clinical services at one of the performance sites listed in Item b above? ☐Yes ☒No
If Yes, Fiscal Approval Process (FAP)-designated units complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP, see www.uab.edu/ohr.

d. Is this a field study? ☐Yes ☒No
If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors:____

e. Is the study to be undertaken within a school, business, or other institution that does not have an institutional review board? ☐Yes ☒No
If Yes, attach a statement of any contacts with and approvals from the appropriate institution officials.
Note. Documentation of all such approvals must be received by the UAB OIRB before IRB approval will be issued.

f. Has this protocol or project been reviewed by another IRB, similar review board, or departmental review committee(s) that authorizes the use of its patient populations? ☐Yes ☒No
If Yes, provide name of the review board(s):____ and for each board listed, enter either the date of latest approval(s) or "PENDING":____ or reasons not approved:____. *If this protocol is subsequently rejected or disapproved by another review board, the UAB IRB must be notified promptly.*
Attach copies of approvals/disapprovals.

g. Will any of the participants be from the Birmingham Veterans Affairs Medical Center? ☐Yes ☒No

If Yes, attach VA IRB approval or notification from the VA Research and Development Department that the study has been submitted to the VA IRB for review.

h. Will the study be conducted at or recruit participants from the Jefferson County Department of Public Health (JCDH)? ☐Yes ☒No
If Yes, attach notification that the protocol has been approved by JCDH or the Alabama Department of Public Health IRB.

6. Multi-Site Studies

a. Is the investigator the lead investigator of a multi-site study? ☐Yes ☒No
b. Is UAB a coordinating site in a multi-site study? ☐Yes ☒No
c. If you answered **Yes** to *a* or *b*, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, the following items:

- IRB approvals from other sites
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- Interim results.
- Protocol modifications.

Any IRB approvals required from any other sites participating will be sent to the UAB IRB.

7. Drugs: Will any drugs or supplements be used/studied in this protocol? ☐Yes ☒No
If Yes, attach the Drug Review Sheet.

8. Devices: Will any devices be studied in this protocol or used for a purpose other than for which they were approved by the FDA? ☐Yes ☒No
If Yes, attach the Device Review Sheet.

9. Special Approvals

a. Does this project involve the use of radioisotopes? ☐Yes ☒No
If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this project include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No
If Yes, attach documentation of approval from Chairman of the Infection Control Committee of the appropriate facilities.

c. Does this project involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this project require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No
If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this project use stored (existing) specimens from a repository? ☐Yes ☒No
If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled:____

10. Use of Specimens

Does this project involve collecting specimens from participants and storing them for future research? ☐Yes ☒No

If Yes, complete a-h. If no, skip to Item 11

a. How will specimens be obtained, processed, distributed, and stored?

____

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)?

____

c. How will clinical data associated with the specimens be collected and stored?

____

d. What participant-identifying information will be collected and linked to the specimens?

____

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens).

____

f. Will specimens be shared with other investigators in the future? ☐Yes ☐No
If Yes, what identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? Also **if yes**, outline your procedure for assuring IRB approval for release and use prior to release of specimens.

____

Note. Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

g. Will biological samples be stored for future use? ☐Yes ☐No
If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases.

____

h. Is genetic testing planned? ☐Yes ☐No
If Yes, describe the planned testing here and see "DNA/Genetic Testing" in the Guidebook for consent requirements.

____

11. Gene Therapy

Does this project involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No

If Yes, submit the Gene Therapy Project Review Panel Report –OR- If this is a vaccine trial that is exempt from the NIH Guidelines For Research Involving

Recombinant DNA Molecules, submit the Protocol Oversight Review Form For Clinical Vaccine Trials.

12. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "personal health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No

If Yes, complete a-e as described.

a. Will the data/information be stored or managed electronically (on a computer)? ☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution). ☐Yes ☒No

If Yes, attach copy of privacy notices from institution/entity, and provide the name of institution/entity:____

c. Indicate which, if any, of the listed entities below would provide information or maintain health information collected for this protocol and/or where health information that been collected will be stored/maintained.

- ☐ The Kirklin Clinic
- ☐ University of Alabama Hospital
- ☐ The Children's Hospital of Alabama
- ☐ Callahan Eye Foundation Hospital
- ☐ UAB Highlands
- ☐ Jefferson County Department of Health
- ☒ School of Dentistry
- ☐ School of Health Professions
- ☐ School of Medicine
- ☐ School of Nursing
- ☐ School of Optometry
- ☐ University of Alabama Health Services Foundation
- ☐ UAB Health Centers
- ☐ Viva Health
- ☐ Ophthalmology Services Foundation
- ☐ Valley Foundation
- ☐ Medical West - UAB Health System Affiliate

Health System Information Systems:

- ☐ HealthQuest
- ☐ Cerner Millennium (Lab, Radiology, UED, Surgery)
- ☐ EMMI - Master Member Index
- ☐ Horizon - IPV (IVR/CDA/CRIS)
- ☐ CareFlow Net
- ☐ Eclipsys (PIN)
- ☐ IMPACT
- ☐ None—**If None, skip to Item 13.**

d. Indicate which of the listed identifiers would be associated/linked with the protected health information (PHI) used for this protocol.

- ☒ Names
- ☒ Geographic subdivisions smaller than a State
- ☒ Elements of dates (except year) related to an individual
- ☒ Telephone numbers
- ☒ Fax numbers
- ☒ Email addresses
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers
- ☐ Device identifiers and serial numbers
- ☐ Biometric identifiers
- ☐ Web universal resource locators (URLs)
- ☐ Internet protocol address numbers
- ☐ Full-face photographic images
- ☐ Any other unique identifying number—Describe:____

  Note. Codes are not identifying as long as the researcher cannot link the data to an individual
- ☐ None—**If None, skip to Item 13.**

e. Choose one plan to describe your use of the personal health information:

- ☐ The data collected meet the specifications for a "limited data set"
  —Attach Data Use Agreement or Business Associate Agreement
- ☐ Research staff will obtain authorization from each patient to use the information
  —Attach Patient Authorization form, complete except for patient name and IRB protocol number
- ☒ PI requests Waiver of Patient Authorization to use the information
  —Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.
- Number each page of the Human Subjects Protocol (i.e., Page *X* of *Y*).

13. Purpose—in nontechnical, lay language

Summarize the purpose and objectives of this protocol, including any related projects, in one short paragraph.

The purpose of this study is to administer a questionnaire to gather new information since the earlier administration of the DPBRN Enrollment Questionnaire (obtained via UAB IRB approval number X040903006 (Dental PBRN Network Chair). Responses from this questionnaire will be linked with the information collected in the enrollment questionnaire.

14. Background—in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the formulation of this study. Include any relevant past or current research by the Principal Investigator. For drug and device studies summarize the previous results (i.e., Phase I/II or III studies).

This study will query practitioner-investigators in the "Dental Practice-Based Research Network" ("Dental PBRN" and "DPBRN"). The DPBRN is a group of outpatient dental practices that have affiliated to investigate research questions and to share experiences and expertise. To date, 1,000+ dentist and hygienist practitioner-investigators have completed a 101-item enrollment questionnaire.

15. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB? **approximately 700; a total of 1,100 will be asked to participate**

If multi-center study, total number at all centers: n/a

The questionnaire will be administered to all DPBRN practitioner-investigators who have completed one or more DPBRN studies.

b. Describe the characteristics of anticipated or planned participants.

Sex: **Dentistry is a profession performed by both men and women; therefore, both genders will be eligible to enroll. Based on the enrollment questionnaires completed by DPBRN practitioner-investigators, 14% are female.**

Race/Ethnicity: **Racial and ethnic minorities will be included in the study proportional to their composition in the dental community. The racial and ethnic distribution of practitioners expected to participate in the study is approximately 10% will be of a racial/ethnic minority group.**

Age: **22 years of age or older**

Health status: **There is no enrollment criterion having to do with health status.**

Note. If data from prior studies indicate differences between the genders or among racial/ethnic groups in the proposed research or if there are no data to support or to negate such differences, Phase 3 clinical trials will be required to include sufficient and appropriate entry of gender and racial/ethnic subgroups so that trends detected in the affected subgroups can be analyzed. If ethnic, racial, and gender estimates are not included in the protocol, a clear rationale must be provided for exclusion of this information. If prior evidence indicates that the results will not show gender or racial differences, researchers are not required to use gender or race/ethnicity as selection criteria for study participants. They are, however, encouraged to include these groups. See Section II. Policy of the NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH – Amended, October, 2001) for further details.

c. From what population(s) will the participants be derived?

This study will be open to all practitioner-investigators in The Dental PBRN who have completed one or more DPBRN studies. Subjects who participate in the studies will be dentists or dental hygienists who meet eligibility criteria and who provide tacit informed consent to participate. No gender or racial/ethnic group will be excluded.

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants:
The questionnaire will be administered to all DPBRN practitioner-investigators who have completed one or more DPBRN studies. DPBRN maintains that data base, which includes the providers' contact information.
Describe the inclusion/exclusion criteria:
The only criterion is that the person have done one or more DPBRN studies.

d. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.
The questionnaire will be administered to all DPBRN practitioner-investigators who have completed one or more DPBRN studies. No other strata are necessary.

e. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.
- ☒ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- ☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- ☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- ☐ Prisoners: Attach SPRF—Prisoners
- ☐ Minors (<19 years old): Attach SPRF—Minors
- ☒ Employees or students at institution where research conducted
- ☐ Persons who are temporarily decisionally impaired
- ☐ Persons who are permanently decisionally impaired (e.g., mentally retarded)
- ☒ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion:
Practitioners who enroll in this study may coincidentally be pregnant at the time of the study.

A small number of Dental PBRN practitioner-investigators in Alabama are UAB School of Dentistry Faculty and it is possible that some who enroll in this study will be UAB employees.

Danish, Norwegian and Swedish speaking practitioners will enroll in this study. All of the Scandinavian practitioner-investigators in DPBRN speak English and have completed English versions of the DPBRN Enrollment Questionnaire. Scandinavia also uses English data collection forms in other DPBRN studies. There is no need to translate this Infrastructure Update Questionnaire into these other languages.

f. List any persons other than those directly involved in the study who will be at risk. If none, enter "None":**None**

g. Describe the process (e.g., recruitment, chart review) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of

Authorization for Recruitment/Screening. (See http://main.uab.edu/show.asp?durki=61981.)
DPBRN practitioner-investigators will be invited to participate in this study by mail and/or e-mail with a brief explanation of the study. The invitation letter is attached. The data collection for this study will be performed through an online questionnaire. An opportunity will be provided to have any questions answered by the DPBRN Research Coordinators by telephone or e-mail.

Dentists who fail to respond to this invitation to complete the online questionnaire will receive a reminder letter, by mail or e-mail, four weeks after the first initial invitation is sent. This will be repeated four weeks later, in the form of a telephone call, mail, or email, at the discretion of the Regional Coordinator. This last mailing (3rd) may also include a hard copy questionnaire. We may provide both options of completing the questionnaire online or completing the hardcopy questionnaire included with the 3rd mailing. If the practitioner-investigator has not responded by then, we will assume that he or she does not want to participate. The Informed Consent form comprises the Introductory letter that will be mailed or emailed. Submitting electronically a completed online questionnaire or returning by postal mail a completed hard copy questionnaire constitutes verification of consent. We will mail or take to the dental office the hard copy questionnaire for dentists who request a hard copy version.

h. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., databases) from which you will recruit participants.
The participants directly involved in this study are the practitioner-investigators who will be answering an online questionnaire. Subjects will be recruited from the Dental PBRN and need to meet the eligibility criteria specific to this protocol and provide informed consent to participate. The Informed Consent form comprises the Introductory letter that will be mailed by post and/or by email. This form has been attached. Submitting electronically a completed online questionnaire or returning a hard copy questionnaire by postal mail constitutes verification of consent

i. Describe the procedures for screening potential participants.
The online questionnaire will be administered to all DPBRN practitioner-investigators who have completed one or more DPBRN studies.

16. Protocol Procedures, Methods, and Duration of the Study—in nontechnical language

a. Describe the study methodology that will affect the participants—particularly in regard to any inconvenience, danger, or discomfort.
The only inconvenience to the participant is the time required for the practitioner-investigator to complete the online study questionnaire or the hard copy questionnaire.

b. What is the probable length of time required for the entire study (i.e., recruitment through data analysis to study closure)? **The total duration of the study is estimated to be 7 months. After mail and e-mail invitation(s) are sent to all DPBRN eligible persons, it is expected that the duration of the study will be 3 months, including the time for two follow-up mailings. The remaining study time will be devoted to data analysis and manuscript preparation.**

c. What is the total amount of time each participant will be involved?
The amount of time involved is the time it takes for the participant to complete the online questionnaire or the hard copy questionnaire. The approximate time is 30 minutes.

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "not applicable."

This study only involves one phase – completing the online questionnaire or hard copy questionnaire is preferred.

e. List the procedures, the length of time each will take, and the frequency of repetition, and indicate whether each is done solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population. *Insert additional table rows as needed.*

Procedure	Length of Time Required of Participants	Frequency of Repetition	Research (Res) –OR- Routine Care
Practitioner-investigator reads Introductory information, completes online Questionnaire or hard copy questionnaire and submits	**30 min**	**0**	☒Res ☐ Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No
If Yes, attach a copy.

There is a practitioner online and hard copy questionnaire for this study.

g. Will participants incur any costs as a result of their participation? ☐Yes ☒No
If Yes, describe the reason for and amount of each foreseeable cost.

h. Will participants be compensated? ☒Yes ☐No
If Yes, complete i-v:
i. Type: (e.g., cash, check, gift card, merchandise): **check**
ii. Amount or Value: **$50.00**
iii. Method (e.g., mail, at visit): **mail**
iv. Timing of Payments: (e.g., every visit, each month): **Participants will be required to have checked a box as the last question of the survey to verify that they want remuneration. This is advisable because in previous surveys some DPBRN practitioners-investigators have written on the questionnaire that they do not want payment. Remuneration will be made after clarification has been made on any unclear responses on the study questionnaire.**
v. Maximum Amount of Payments per Participant: **$50.00**

17. Describe the potential benefits of the research.

Subjects may benefit from the opportunity to reflect their views and gain information on the practice methods of their peers. The indirect benefit to the patients of the subjects answering the questionnaire may be ultimate improvements in dental treatment in daily clinical practice. The potential benefits to the subjects and indirectly to their patients will far exceed the risk involved with the participation.

18. Risks

a. List the known risks—physical, psychological, social, economic, and/or legal—that participants may encounter as a result of procedures required in this protocol. Do not list risks resulting from standard-of-care procedures. *Note. Risks included in this protocol document should be included in the written consent document.*
The only risk to the participating subjects will be the highly unlikely accidental disclosure of health care provider information. However, every precaution will be taken to prevent this. No additional exposure is expected from this protocol.

b. Estimate the frequency, severity, and reversibility of each risk listed.
None

c. Is this a therapeutic study or intervention? ☐Yes ☒No

If Yes, complete the following items:

i. Describe the standard of care in the setting where the research will be conducted:____

ii. Describe any other alternative treatments or interventions:____

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using:____

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No

If Yes, describe the provisions that have been made to make these resources available.

____

e. Do the benefits or knowledge to be gained outweigh the risks to participants? ☒Yes ☐No

If No, provide justification for performing the research:____

19. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

Because this study targets practitioner-investigators and not specific patients, this study is considered to have minimal risk to dental patients. Practitioner-investigators will be identified in any dataset by network-provided ID codes.

If study involves drugs or devices skip Items 19.b. and 19.c., go to Item 20, and complete the Drug or Device Review Sheet, as applicable.

b. If hazards to an individual participant occur, describe (i) the criteria that will be used to decide whether that participant should be removed from the study; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

NA

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire study and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants.

NA

20. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒**Yes** ☐**No**

If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent for this protocol? ☐**Yes** ☒**No**

If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? **The only human subjects directly involved in this study are the practitioner-investigators who will be answering an online or hard copy questionnaire. Subjects will be recruited from the Dental PBRN and need to meet the eligibility criteria specific to this protocol and provide informed consent to participate. The Informed Consent form comprises the Introductory letter that will be mailed by post or by email. Submitting electronically a completed online questionnaire or returning a hard copy questionnaire by postal mail constitutes verification of consent**.

d. Who will conduct the consent interview? **NA**

e. Who are the persons who will provide consent or permission? **The only human subjects directly involved in this study are the practitioner-investigators who will be answering an online questionnaire or a hard copy questionnaire. Subjects will be recruited from the Dental PBRN and need to meet the eligibility criteria specific to this protocol. Submitting electronically a completed online questionnaire or returning a hard copy questionnaire by postal mail constitutes verification of consent**.

f. What steps will be taken to minimize the possibility of coercion or undue influence? **We will provide the study participants information that explains the nature of the study, time commitment involved, any risks involved, and compensation information. We will also answer any questions they may have in a telephone conversation, face-to-face, and/or e-mail discussion with them.**

g. What language will the prospective participant or the legally authorized representative understand? **English**

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "no such effect."
No such effects.

j. If any project-specific instruments will be used in the consenting process, such as flip charts or videos, describe the instrument(s) here, and provide a copy of each. If not, enter "not used."
An Invitation letter (attached) inviting the practitioner to participate will be mailed or sent by e-mail.

k. How long will participants have between the time they are told about the study and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **Dentists who fail to respond to this invitation to complete the online questionnaire will receive a reminder letter, by mail or e-mail, four weeks after the first invitation is sent. This will be repeated four weeks later, in the form of a telephone call, mail, or email, at the discretion of the Regional Coordinator. This last mailing (3rd) may also include a hard copy questionnaire. We will provide both options of completing the questionnaire online or completing the hardcopy questionnaire included with the 3rd mailing. If the practitioner-investigator has not responded by then, we will assume that he or she does not want to participate.**

21. Procedures to Protect Privacy

Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear your conversation with potential participants, individuals will not be publicly identified or embarrassed).
We will provide the study participants information that explains the nature of the study, time commitment involved, any risks involved, and compensation information. We will also answer any questions they may have in a telephone conversation, face-to-face and/or e-mail discussion with them. All information will be provided online or by a hard copy by the study participant.

22. Procedures to Maintain Confidentiality

a. Describe the manner and method for storing research data and maintaining confidentiality. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the departmental and all computer systems used to store protocol-related data, and describe how access to that data will be limited to those with a need to know.
Practitioner-investigators will not have access to the data. Only certain personnel in the Dental PBRN Coordinating Center will have access to the data. Electronic data will be located on a secure network drive with restricted access. The general operation of the Dental PBRN Coordinating Center has IRB approval via X050318008 ("Dental PBRN Coordinating Center").

b. Will any information derived from this study be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☒Yes ☐No
If Yes, complete i-iii.
i. To whom will the information be given? **At the conclusion of the study the network members will receive a final report of the study results. In addition, the outcomes of the study will be disseminated to the Network as well as to the dental profession as a whole in a number of ways: 1) article in the Network newsletter, 2) news articles placed on the Network Website, 3) presentation at the network annual meeting and scientific conferences, and 4) articles in scientific journals.**

ii. What is the nature of the information? **Data will be obtained from the responses given by the practitioner-investigators who will be answering the online questionnaire or a hard copy questionnaire. Information about the Dental PBRN practitioner-investigators and their practices have been already gathered as part of the enrollment process.**

iii. How will the information be identified, coded, etc.? **Within DPBRN, the practitioner-investigators may be identified by name in order to link information about study and meeting participation. However, all data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator. All data will be presented in the aggregate and we will review results to make sure that there are no "small cells" in the output that could potentially identify a survey participant. Because this study targets practitioner-investigators and not specific patients, this study is considered to have minimal risk to dental patients. Practitioner-investigators will be identified by network-provided ID codes so specific changes within practitioner can be tracked.**

23. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None."

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

School of Dentistry

Institutional Review Board
Protocol Oversight Review Form

Date Submitted to IRB: **October 20, 2010**

Title of Project: **Infrastructure Update Survey (Dental PBRN Network Chair)**

Name of Principal Investigator: **Gregg H. Gilbert, DDS, MBA**

Signature of Principal Investigator: _____

School: **School of Dentistry**
Department: **General Dental Sciences**
Division: **Dental**

Review Process (as determined by Department Chair):

- ☒ Departmental Review
- ☐ Divisional Review (Division Director or Designate)
- ☐ Center or Departmental Protocol Review Committee Review
- ☐ Project Review Panel (PRP)—Appointed by the Department Chairman or Division Director (PRP report attached)

I have reviewed the proposed research and concluded that the following apply:

- The research is scientifically valid and is likely to answer the scientific question;
- The researcher and the study team are qualified and/or credentialed to conduct the procedures proposed;
- The researcher has identified sufficient resources in terms of experienced research personnel, facilities, and availability of medical or psychological services that may be necessary as a consequence of participation in the research to protect the research participants.

Name of Official: **Kenneth Tilashalski, DMD**
Title: **Associate Professor**
(type or print)

Signature: Kenneth Tilashalski DMS Date: 10/20/10

General Dental Sciences
111 School of Dentistry Building
1919 7th Avenue South
205.934.5423
Fax 205.975.0603

The University of
Alabama at Birmingham
Mailing Address:
SDB 111
1530 3RD AVE S
BIRMINGHAM AL 35294-0007

Special Population Review Form—
Pregnant Women, Fetuses, Neonates/Nonviable Neonates

Title of Protocol: **Infrastructure Update Survey (Dental PBRN Network Chair)**

1. State reasons for including this population in your project: **Some of the dental practitioners to participate in this study may coincidentally be pregnant at the time the questionnaire is completed.**

2. Will the project meet the health needs of the mother/fetus? ☐ Yes, ☒ No

OR

Is the risk to the fetus minimal and the least possible risk for achieving the objectives? ☒ Yes, ☐ No

3. If the project involves a termination of a pregnancy,

Will the investigators and staff remove themselves from any decisions related to the termination, including determining the fetus' viability? ☐ Yes, ☐ No NA

and

Are there inducements, monetary or otherwise, offered? ☐ Yes, ☐ No

4. If the project involves pregnant women,

Will the project meet the health needs of the mother and will the fetus be placed at risk only to the minimum extent necessary? ☐ Yes, ☐ No NA

5. If the project involves in utero fetuses,

Will the project meet the needs of the fetus and will the risk to the fetus be minimal? ☐ Yes, ☐ No NA

OR

Will the risk to the fetus be minimal and the purpose of the project is to develop important biomedical knowledge that cannot be obtained by other means? ☐ Yes, ☐ No NA

6. If the project involves ex utero fetuses,

Will there be no added risk to the fetus and the purpose of the project is to develop important biomedical knowledge that cannot be obtained by other means? ☐ Yes, ☐ No NA

OR

Is the project's purpose to enhance the possibility of survival of the fetus or neonate to the point of viability? ☐ Yes, ☐ No NA

PI Name: **Gregg H. Gilbert** PI Signature: _____ Date: 10/20/2010

[redacted] Waiver of Informed Consent Documentation

- **Use this form** to request a waiver of the requirement
  - to obtain a signed consent document (cannot be used for FDA-regulated research) or
  - to give participants a signed copy of the document.
- **Do not use this form** to request a waiver of part or all of the informed consent process. Instead, use the Waiver of Consent or Waiver of Authorization and Informed Consent.

1. IRB Protocol Title: ***Infrastructure Update Survey (Dental PBRN Network Chair)***

2. Principal Investigator: ***Gregg H. Gilbert, DDS, MBA***

3. Choose one of the checkboxes below, indicating why the waiver of documentation is being requested for this research, and provide protocol-specific details as requested.

☐ Confidentiality Risk—Respond to Items a-c, below.

a. Would the only record linking the subject and the research be the consent document? ☐Yes ☐No

b. Would the principal risk be the potential harm resulting from a breach in confidentiality? ☐Yes ☐No

c. Describe your plans to ask each subject whether he/she wants documentation linking his/her name with the research, and how each subject's wishes will govern (e.g., a document could be used for the informed consent process, subjects would be asked if they wanted a signed copy to document their consent, and those who did not would receive an unsigned copy).____

☒ The research involves no greater than minimal risk and no procedures for which written consent is normally required outside the research context. Respond to Item a, below.

a. Describe plans, if any, that you have for providing subjects with a written statement regarding the research. (*Note: The IRB may require that a written statement be given to the subject.*) **Because this study targets practitioner-investigators and not specific patients, this study is considered to have minimal risks. We will provide the study participants information that explains the nature of the study, time commitment involved, any risks involved, and compensation information. We will also answer any questions they may have in a telephone conversation or in face-to-face discussion with them if necessary.**

By signing this request for waiver of informed consent documentation, I certify the information included in it.

[redacted]
Principal Investigator's Signature

10/20/2010
Date

Waiver of Authorization and Informed Consent

- **Use this form** to request a waiver of patient authorization to use protected health information (PHI) in research. Complete Items 1-4. To also request a waiver of informed consent, complete Item 5.
- **Do not use this form** to request a waiver of informed consent when HIPAA does not apply. Instead, use the Waiver of Informed Consent form.
- **Do not use this form** if the research or a demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs. Instead, contact the Office of the UAB IRB (934-3789).

1. IRB Protocol Title: **Infrastructure Update Survey (Dental PBRN Network Chair)**

2. Principal Investigator: **Gregg H. Gilbert, DDS, MBA**

3. Request to Waive HIPAA Authorization for Research. Provide protocol-specific responses to the following items that describe why the waiver is being requested for this use of PHI in this research.

   a. The use/disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals.
   i. Describe the plan to protect the identifiers from improper use and disclosure:
   Within DPBRN, the practitioner-investigators may be identified by name in order to link information about the study participation. However, all data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator. All data will be presented in the aggregate and we will review results to make sure that there are no "small cells" in the output that could potentially identify a survey participant. Because this study targets practitioner-investigators and not specific patients, this study is considered to have minimal risk to dental patients.

   ii. Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law:
   All data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator. All data will be presented in the aggregate and we will review results to make sure that there are no "small cells" in the output that could potentially identify a survey participant.

   b. Describe why the research cannot practicably be conducted without the waiver or alteration of patient authorization to use PHI in research:
   The questionnaire will be completed online and consent will be inferred when practitioner-investigators have completed the questionnaire. Within DPBRN, the practitioner-investigators may be identified by name in order to link information about the study participation. However, all data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator.

   c. Describe why the research cannot practicably be conducted without access to and use of the PHI:
   Within DPBRN, the practitioner-investigators may be identified by name in order to link information about the study participation. However, all data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator. It is crucial to

be able to identify specific individuals before merging responses into a single data set in which identifiers have been removed.

4. Non-UAB Disclosure or Use of PHI

Do you plan to use the waiver from the UAB IRB to justify disclosure or use of PHI from a non-UAB covered entity? Yes ☐ No☒

If yes, complete a and b.

a. What covered entity or entities will disclose or use the PHI? ____

b. What PHI will the entity or entity disclose or use? ____

If the IRB approves this request for waiver, the PI can forward the IRB-issued waiver to the non-UAB covered entity as documentation of the waiver of authorization for the disclosure of PHI to UAB. Please note the entity may or may not accept the IRB's waiver and may request an additional review.

5. Request to Waive or Alter Informed Consent Along with HIPAA Authorization

- Complete this item only if you are requesting a waiver or alteration of informed consent along with the waiver of HIPAA authorization.

Provide protocol-specific responses to the following four items that describe why the waiver of consent is being requested along with this use of PHI in this research.

a. Describe why the research involves no more than minimal risk to the subjects:

b. Describe why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

c. Describe why the research could not practicably be carried out without the waiver or alteration of informed consent:

d. Describe how, whenever appropriate, the subjects will be provided with additional pertinent information after participation:

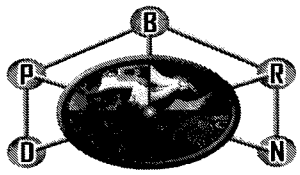
By signing this request for waiver of patient authorization, I certify that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ Check here if also requesting waiver of informed consent.

Principal Investigator's Signature

The investigator's original signature is required.

10/20/2010
Date



Dental Practice-Based Research Network
www.DentalPBRN.org

Dear **<name of practitioner>**,

We invite you to participate in an important study from The Dental PBRN. Your participation would comprise completing an online questionnaire. The questionnaire has to do with clinician and practice characteristics, information technology, how you utilize dental staff, and what your opinions are about new types of dental providers that some U.S. states are considering.

You may recall that DPBRN was funded by the National Institutes of Health from 2005-2012. We will be required to submit a "competing renewal" application in 2011. Obtaining updated information about your practice will be very important to preparing this application.

To complete the online questionnaire please visit our website at www.DentalPBRN.org.

Simply click on the **"Infrastructure Update" link** at the bottom left part of the page. Then follow the instructions from there.

You will need to enter your individual identification (ID) code. As a check that we placed the correct letter in this envelope, please verify that your name is indeed the one that appears at the top of this letter. If not, please call or email our Program Manager listed below.

Your ID code is **<XXXXXX>** and the study code is **"update"** (without the quotation marks).

We estimate that completing this survey will take up to 30 minutes, for which you or your organization will receive $50 if you check a box at the end of the survey agreeing to this. To receive the $50, ordinarily we would need you to complete a "W-9 form". However, almost all of you have completed one already for us, so we will contact you only if we need one from you. It will take a few weeks to get your payment because it takes the paperwork a while to get cleared through the university system.

This is your third notification for this survey. This time, we have included a printed version of the survey in case you prefer to fill out the printed version. We prefer that you do the online version, but returning the printed version is OK, too. Please do not fill out *both* the online version and the printed version.

Your input is important to us, so if you have not already taken the survey, please do so today.

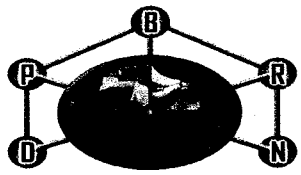
Records of your participation will be kept confidential. Only authorized personnel will have access to data, and all information, whether electronic or in paper form, will be stored in a secure manner. This information will not be sold, used for any reason other than research, released to any insurance company, or released to any other similar interest. Although the UAB's Institutional Review Board (IRB) has reviewed and approved the questionnaire, it has the authority to inspect completed questionnaires to ensure that we have complied with IRB procedures. Results may be published for scientific purposes, but your identity will not be revealed. Only statistical summaries will be presented.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Sheila Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB) at the University of Alabama at Birmingham (UAB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Thank you! If you have any questions about this research, please call or email the Program Manager, Andrea Mathews at (205) 934-2578 or ahmathews@uab.edu, or you may also call the DPBRN Network Chair, Dr. Gregg Gilbert at (205) 934-5423. Thank you!

With regards,

The Dental PBRN Executive Committee



Dental Practice-Based Research Network
www.DentalPBRN.org

Dear **<name of practitioner>**,

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Your ID code is **<XXXXXX>** and the study code is **"update"** (without the quotation marks).

We estimate that completing this survey will take up to 30 minutes, for which you or your organization will receive $50 if you check a box at the end of the survey agreeing to this. To receive the $50, ordinarily we would need you to complete a "W-9 form". However, almost all of you have completed one already for us, so we will contact you only if we need one from you. It will take a few weeks to get your payment because it takes the paperwork a while to get cleared through the university system.

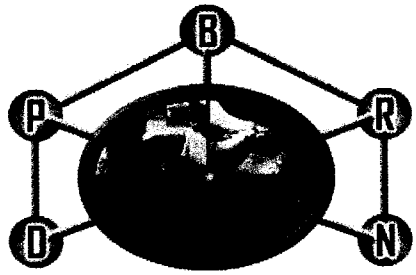
Records of your participation will be kept confidential. Only authorized personnel will have access to data, and all information, whether electronic or in paper form, will be stored in a secure manner. This information will not be sold, used for any reason other than research, released to any insurance company, or released to any other similar interest. Although the UAB's Institutional Review Board (IRB) has reviewed and approved the questionnaire, it has the authority to inspect completed questionnaires to ensure that we have complied with IRB procedures. Results may be published for scientific purposes, but your identity will not be revealed. Only statistical summaries will be presented.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Sheila Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB) at the University of Alabama at Birmingham (UAB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Thank you! If you have any questions about this research, please call or email the Program Manager, Andrea Mathews at (205) 934-2578 or ahmathews@uab.edu, or you may also call the DPBRN Network Chair, Dr. Gregg Gilbert at (205) 934-5423. Thank you!

With regards,

The Dental PBRN Executive Committee



Dental Practice-Based Research Network
www.DentalPBRN.org

The questionnaire has to do with clinician and practice characteristics, information technology, how dental staff are utilized in your practice setting, and utilization of new types of dental providers that some U.S. states have established or are considering. Thank you for your participation!

Some questions may not apply to your practice or your role within the practice and may be left blank if necessary.

Once you start the survey, the "Back" button on your browser will be disabled. Instead, please use the "Back" button at the bottom of the survey form.

<u>Please do not hit the "Enter" button</u> on your keyboard to advance to the next page; this may end your survey. Instead, hit the "Next" button at the bottom of the survey form.

You can track how many pages you have completed by looking at the bottom of the screen.

Section 1: About your practice and your patients

1. Which category best describes your practice?

a. Solo private practice (only one dentist in the practice)
b. Group private practice (more than one dentist)
c. HealthPartners Dental Group or Permanente Dental Associates
d. Public health practice, community health center, or publicly-funded clinic
e. Academic setting
f. Other, please specify: _____

2. Are you in the same building or organization with any providers of medical care?

a. Yes, in the same building
b. Yes, in the same organization, but not in the same building
c. No

3. What percent of your patients do you estimate consider your practice their regular source of dental care?

__ % of my patients

4. What percent of your patients do you estimate...

Seek dental care occasionally or regularly, whether or not they have a specific problem	____ % of patients
Seek dental care only when they have a problem of some type	____ % of my patients
	100% [must add to 100%]

5. What percent of your patients do you estimate have a regular source of medical care?

__ % of my patients

6. What percentage of your patients do you estimate have been diagnosed with...

diabetes mellitus of any type	__ %
cardiovascular disease (including hypertension)	__ %

7. In the past month, how many patients have you referred to a physician for evaluation of medical problems?

__ patients referred in the past month (*number* of patients, not percentage)

8. Do you use a computer to manage clinical (as opposed to administrative) patient data?

a. Yes [if yes, then please answer this question...]

8a. What brand do you use?

a. Dentrix
b. Soft Dent
c. Eagle Soft
d. Eagle Dental
e. Practice Works
f. GSD Works
g. Axium
h. Other, please specify: _____

b. No [if no, then please answer this question...]

8b. Within the next two years, how likely are you to begin using a computer to manage clinical patient data?

a. Very likely
b. Somewhat likely
c. Not likely
d. Not sure at this time

9. Please indicate how you store clinical information. If you store information on both paper and computer, please check <u>both</u> categories.

Type of information	Paper	Computer	Not at all
chief complaint	□	□	□
medical history	□	□	□
dental history	□	□	□
progress notes	□	□	□
problem list/diagnoses	□	□	□
treatment plan	□	□	□
completed treatment	□	□	□
dental status	□	□	□
periodontal charting	□	□	□
radiographs	□	□	□
extraoral images or photographs	□	□	□
intraoral images or photographs	□	□	□
appointments	□	□	□
other:_____	□	□	□

10. Would you be willing to use data from your computer system for DPBRN studies, where feasible and allowed by confidentiality regulations, instead of having to enter them separately by hand or sending them to your DPBRN Regional Coordinator?

a. Yes
b. No
c. Don't know

11. Would you be willing to use electronic forms (e.g., a secure system loaded onto your computer, laptop, or tablet PC) rather than paper forms for collecting research data?

a. Yes
b. No
c. Don't know

12. When receiving periodic communication from your DPBRN Regional Coordinator, how do you prefer to be contacted?

a. By personal email
b. By e-mail to a staff member in my practice who will relay the information
c. By personal telephone call
d. By telephone call to a staff member in my practice who will relay the information
e. Through social media (e.g., Facebook, Twitter, LinkedIn)
f. By postal mail
g. Other (please list):_____

13. When receiving a notice of new DPBRN results and network information (e.g., study findings, notice of publications, newsletters), how do prefer to receive this information?

a. By e-mail
b. Printed, sent by postal mail
c. Through social media (e.g., Facebook, Twitter, LinkedIn)
d. Other (please list):_____

14. Do you do personally do any root canal procedures?

a. Yes [if yes, then please answer these questions...]

14a. On what percent of these root canals do you estimate that you use a rubber dam?

a. None
b. Less than 25%
c. 25% - 50%
d. 51% - 75%
e. More than 75%, but less than 100%
f. All of them

14b. Do you use any other type of isolation?

a. Yes; please specify _____
b. No

b. No

Section 2: Types of dental staff

In this survey, the term "expanded function" means activities that dental hygienists and dental assistants cannot do in all U.S. states or Scandinavian countries.

Examples of "expanded duties" for dental hygienists and dental assistants would include cavity preparation for simple dental restorations, administering local anesthetic injections, re-cementing permanent crowns, extracting primary teeth or comparable procedures.

15. Please indicate if your practice setting employs any of the following dental providers:

	Check if your practice employs ...	Check if your practice does not employ...
a. Associate Dentist(s)	☐	☐
b. Expanded Function Dental Hygienist(s) (EFDH)	☐	☐
c. Dental Hygienist(s)	☐	☐
d. Expanded Function Dental Assistant(s) (EFDA)	☐	☐
e. Dental Assistant(s)	☐	☐

16. Please indicate all the personnel in your office who do each procedure (MARK ALL THAT APPLY):

	No one does this procedure in my practice setting.	A dentist does this in my practice setting.	A dental hygienist does this in my practice setting.	A dental assistant does this in my practice setting.
Oral health education and prevention	☐	☐	☐	☐
Take radiographs	☐	☐	☐	☐
Take impressions	☐	☐	☐	☐
Apply topical medications (e.g., topical fluoride, bleaching agents and cavity varnishes)	☐	☐	☐	☐
Etch enamel surfaces, apply pit and fissure sealants	☐	☐	☐	☐
Place and remove rubber dam	☐	☐	☐	☐
Fabricate athletic mouth guards	☐	☐	☐	☐
Denture soft relines	☐	☐	☐	☐
Remove supra-gingival deposits	☐	☐	☐	☐
Remove sub-gingival deposits	☐	☐	☐	☐
Perform root curettage	☐	☐	☐	☐
Remove excess cement	☐	☐	☐	☐
Place temporary fillings	☐	☐	☐	☐

	No one does this procedure in my practice setting.	A dentist does this in my practice setting.	A dental hygienist does this in my practice setting.	A dental assistant does this in my practice setting.
Cement and adjust temporary restorations	☐	☐	☐	☐
Re-cement permanent crowns	☐	☐	☐	☐
Cavity excavation and preparation for simple permanent restorations	☐	☐	☐	☐
Place, carve and adjust restorations	☐	☐	☐	☐
Suture removal	☐	☐	☐	☐
Extract primary teeth	☐	☐	☐	☐
Administer local anesthetic	☐	☐	☐	☐
Administer nitrous oxide inhalation	☐	☐	☐	☐

17. Have you ever worked with or employed an Expanded Function Dental Hygienist or Expanded Function Dental Assistant who was certified to perform care in areas beyond what is normally allowed (e.g., restorative functions, local anesthesia, administration of nitrous oxide)?

a. Yes
b. No

18. Would you say that your level of experience working with expanded function Dental Hygienists and/or expanded function Dental Assistants is:

a. Much more than average
b. Somewhat more than average
c. About average
d. Somewhat less than average
e. Much less than average

19. Do you think that expanded function dental hygienists or expanded function dental assistants have a positive or negative impact on the provision of quality dental care?

a. Very positive
b. Positive
c. Somewhat positive
d. Somewhat negative
e. Negative
f. Very negative
g. Don't know

Section 3: Expanding duties of non-dentist providers

Dental therapists are dental providers who deliver a limited set of preventive, therapeutic and basic restorative services. In some countries, they have been recognized dental providers for some time, but in the United States it is a new provider type. Currently only the state of Minnesota recognizes this provider.

20. How informed are you about the dental therapist provider?

a. Not at all – I have never heard of It [please skip to Question #23]
b. A little
c. Somewhat
d. Moderately
e. Very

21. The following are statements about potential impacts that dental therapists could have on dentists. For each one, please indicate the extent to which you agree or disagree with each statement

	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree	Don't Know
a It would disrupt the relationship I have with my patients	□	□	□	□	□
b. It would free up time for me to focus on more complex and interesting dental procedures	□	□	□	□	□
c. The administrative burden would not be worth it	□	□	□	□	□
d. I would trust the quality of their work in all areas for which they are trained	□	□	□	□	□

22. Do you think that dental therapists will have a positive or negative impact on the provision of quality dental care?

a. Very positive
b. Positive
c. Somewhat positive
d. Somewhat negative
e. Negative
f. Very negative
g. Don't know

23. Is your practice in the state of Minnesota?

a. Yes [go to question 24M]
b. No [go to question 24]

MINNESOTA ONLY SECTION:

24M. The first class of dental therapists will graduate in Minnesota in 2011. How likely is it that your practice will consider hiring a dental therapist?

a. Very unlikely
b. Somewhat unlikely
c. Somewhat likely
d. Very likely

25M. A specific aspect of the legislation passed was in response to access to dental care in the state of Minnesota. What impact do you think dental therapists will have on access to dental care in Minnesota?

a. Decrease access
b. Somewhat decrease access
c. Have no impact on access
d. Somewhat increase access
e. Increase access
f. Don't know

26M. When deciding whether to hire a dental therapist, how important do you think the following factors are:

	Not important	A little important	Somewhat important	Very important
a. Issues associated with liability insurance	□	□	□	□
b. The nature of the contractual agreement between the dentist and dental therapist	□	□	□	□
c. Whether the dental therapist has experience and/or licensure as a dental assistant	□	□	□	□
d. Whether the dental therapist has experience and/or licensure as a dental hygienist	□	□	□	□

27M. The following are potential barriers to hiring a dental therapist. For each one, please indicate how much of a barrier it would be for your practice if you were to consider hiring a Dental Therapist.

	BIG BARRIER	MODERATE BARRIER	SMALL BARRIER	NOT A BARRIER	DON'T KNOW
a Space	□	□	□	□	□
b Overhead Costs	□	□	□	□	□
c Patient Acceptance	□	□	□	□	□
d Demand for the services they would provide	□	□	□	□	□
e Added supervisory responsibilities for the Dentist	□	□	□	□	□
f The risk they will leave the practice after they have gained experience	□	□	□	□	□

28M. The Minnesota legislation requires that basic socio-demographic characteristics of the patients seen by dental therapists be reported to the State Board of Dentistry. How much of a concern would this be in the consideration of hiring a dental therapist in your practice setting?

a. Of no concern
b. Of little concern
c. Of some concern
d. Of much concern

NON-MINNESOTA

24. At the current time Minnesota is the only U.S. state that licenses dental therapists. Other states are considering licensing dental therapists. If your state were to license dental therapists, how likely is it that your practice will consider hiring a dental therapist?

a. Very unlikely
b. Somewhat unlikely
c. Somewhat likely
d. Very likely

25. A specific aspect of the legislation passed in Minnesota was in response to access to dental care in the state. If your state were to allow dental therapists to practice, what impact do you think dental therapists would have on access to dental care in your state?

a. Decrease access
b. Somewhat decrease access
c. Have no impact on access
d. Somewhat increase access
e. Increase access
f. Don't know

FOR ALL RESPONDENTS:

26. Please check here if you would like us to send you or your practice organization $50 compensation for completing this survey.

□ yes, please send compensation

Please record here any comments that you think that we should know about: