PREDICT: A PBRN Feasibility Study on COVID-19 Screening in Dental Practice

PREDICT Informed Consent for NCT05123742

This attachment pertains the informed consents for Pro2021000968/ IRB-300007026 (University of Alabama at Birmingham)

- Patients' consent was approved on October 15, 2021
- Dental Health Care Workers' consent was approved on July 21, 2021

CONSENT FORM TO BE PART OF A RESEARCH STUDY: DENTAL HEALTH CARE WORKERS

Title of Research: Pragmatic Return to Effective Dental Infection Control through Triage and Testing (PREDICT) PBRN Feasibility Study

UAB IRB Protocol #: **IRB-300007026**

Principal Investigators: Cecile Feldman, DMD, MBA

Sponsor: National Institutes of Health

General Information	You are being asked to take part in a research study because you work in a dental office. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are described further in the consent form.
Purpose	The purpose of the study is to refine protocols and logistics developed for performing screening and COVID-19 testing in dental offices.
Duration & Visits	Your time in the study will take about 2 hours over one month.
Overview of Procedures	If you take part in the research, you will be asked to complete three screenings for COVID-19, two surveys and complete or receive COVID-19 viral and antibody tests.
Risks	There may be a slight risk of discomfort from the nasal swab, tongue swab, and the finger prick to obtain a blood sample. The most common risk for participating in this study is a possible breach of confidentiality.
Benefits	The benefits of taking part in this study will be receiving free COVID-19 testing and gaining knowledge of your likely COVID-19 status.
Alternatives	Being in this research study is voluntary. You do not have to take part in this study if you don't want to, it is your choice. Not participating will not affect your status as an employee in the participating dental office.

Purpose of the Research Study

We are asking you to take part in a research study. The COVID-19 pandemic has created serious concerns about the return of patients and dental professionals to a dental office. This study is being done to test out methods to be followed in a large scale, multi-practice, clinical study focused on improving the safety of the dental office by improving triage procedures and developing standard COVID-19 testing protocols. Approximately 40 dental healthcare workers (DHCWs), including dentists, dental hygienists, assistants and front desk personnel, are being asked to take part in this study protocol.

Study Participation & Procedures

If you agree to take part in this study, you will be asked to participate in three sessions in the dental office over a one-month period. Participants will be split into 2 groups called Dental Health Care Workers Point of Care (DHCW POC) and Dental Health Care Workers LAB (DHCW LAB). Each group will have slightly different

procedures. Participants will participate in either the DHCW POC or DHCW LAB based upon preference of the Practice Based Research Network dentist.

DAY 1

- You will undergo a an in-office COVID-19 triage screening which includes a series of symptom questions along with a temperature check and pulse oximeter reading. It will take approximately 5 minutes for the in-office triage.
    - Symptom questions ask whether or not you currently have:
        - fever or chills
        - cough
        - shortness of breath or difficulty breathing
        - fatigue
        - muscle and body aches
        - headache
        - loss of taste
        - loss of smell
        - sore throat
        - congestion or runny nose
        - nausea or vomiting
        - diarrhea

- You will complete an electronic questionnaire on a tablet provided by the dental office. It will take approximately 10 minutes to complete the questionnaire.
    - Questions include demographics, PPE used in the office, work practice controls used in the office, importance of triage and testing, importance of PPE measures, perceptions of safety and comfort in the workplace, safety culture in the office, SARS-CoV-2 testing preferences, dentists role in SARS-CoV-2 testing, and willingness to test in the office.

- DHCW LAB participants will complete two COVID-19 viral tests: one that collects saliva and the other tongue cells. For the COVID-19 viral saliva test, you will spit in a tube following manufacturer directions on the package insert, package as directed, and place in the completed test kit collection box in the dental office. For the tongue swab, you will brush the tongue swab along the top of your tongue, place the brush in a tube, and package for specimen pickup. It will take approximately 15 minutes to complete both COVID-19 viral tests.

- DHCW POC participants will complete a COVID-19 Point of Care (POC) test, during which the National Dental PBRN Practitioner will sweep the inside of your nose using a nasal swab to collect your specimen for the COVID-19 test. The National Dental PBRN Practitioner will process the sample in the office and give you the results within 15 minutes. In total, it will take approximately 15 minutes to complete COVID-19 POC test.

- You will complete a COVID-19 Antibody test. You will prick your finger using a sterile lancet to collect a small sample of blood in the Mitra specimen collection cartridge. You will package the Mitra cartridge and place it in the practice collection box to await shipment to Rutgers. It will take approximately 5 minutes to complete the COVID-19 Antibody test.

Day 14 (+/- 7 days)

- You will undergo an in-office COVID-19 triage screening which includes the series of symptom questions along with a temperature check and pulse oximeter reading. It will take approximately 5 minutes for the in-office triage.
    - Symptom questions ask whether or not you currently have:
        - fever or chills
        - cough
        - shortness of breath or difficulty breathing
        - fatigue
        - muscle and body aches
        - headache
        - loss of taste
        - loss of smell
        - sore throat
        - congestion or runny nose
        - nausea or vomiting
        - diarrhea

- DHCW LAB participants will complete two COVID-19 viral tests: one that collects saliva and the other tongue cells. For the COVID-19 viral saliva test, you will spit in a tube following manufacturer directions on the package insert, package as directed, and place in the completed test kit collection box in the dental office. For the tongue swab, you will brush the tongue swab along the top of your tongue, place the brush in a tube, and package for specimen pickup. It will take approximately 15 minutes to complete both COVID-19 viral tests.
- DHCW POC participants will complete a COVID-19 Point of Care (POC) test, during which the National Dental PBRN Practitioner will sweep the inside of your nose using a nasal swab to collect your specimen for the COVID-19 test. The National Dental PBRN Practitioner will process the sample in the office and give you the results within 15 minutes. In total, it will take approximately 15 minutes to complete COVID-19 POC test.

Day 28 (+/- 7 days)

- You will undergo a an in-office COVID-19 triage screening which includes the series of symptom questions along with a temperature check and pulse oximeter reading. It will take approximately 5 minutes for the in-office triage.
    - Symptom questions ask whether or not you currently have:
        - fever or chills
        - cough
        - shortness of breath or difficulty breathing
        - fatigue
        - muscle and body aches
        - headache
        - loss of taste
        - loss of smell
        - sore throat
        - congestion or runny nose
        - nausea or vomiting
        - diarrhea

- DHCW LAB participants will complete two COVID-19 viral tests: one that collects saliva and the other tongue cells. For the COVID-19 viral saliva test, you will spit in a tube following manufacturer directions on the package insert, package as directed, and place in the completed test kit collection box in the dental office. For the tongue swab, you will brush the tongue swab along the top of your tongue, place the brush in a tube, and package for specimen pickup. It will take approximately 15 minutes to complete both COVID-19 viral tests.

- DHCW POC participants will complete a COVID-19 Point of Care (POC) test, during which the National Dental PBRN Practitioner will sweep the inside of your nose using a nasal swab to collect your specimen for the COVID-19 test. The National Dental PBRN Practitioner will process the sample in the office and give you the results within 15 minutes. In total, it will take approximately 15 minutes to complete COVID-19 POC test.

- You will complete a COVID-19 Antibody test. You will prick your finger using a sterile lancet to collect a small sample of blood in the Mitra specimen collection cartridge. You will package the Mitra cartridge and place it in the practice collection box to await shipment to Rutgers. It will take approximately 5 minutes to complete the COVID-19 Antibody test.

- You will complete an electronic questionnaire on a tablet provided by the dental office. It will take approximately 15 minutes to complete the questionnaire.
    - *DHCW End of Study Survey*- Questions include importance of triage and testing, importance of PPE measures, perceptions of safety and comfort in the workplace, safety culture in the office, SARS-CoV-2 testing preferences, dentists role in SARS-CoV-2 testing, willingness to test in the office, and vaccinations
    - *DHCW Participation Survey*- Questions explore perceptions related to study participation including survey and testing logistics

Reportable Diseases:
The designated National Dental PBRN dentist member of the practice, known as the PBRN Practitioner, will be responsible to notify you of COVID-19 related test results in a confidential manner. (If you have been designated the PBRN Practitioner in the dental office, Rutgers study staff will notify you of your of COIVD-19 test results.)

If your LAB or POC SARS- CoV-2 test is positive, you will be referred to your primary care physician for follow-up and further testing.

In addition, if any aspect of the COVID-19 triage screening is positive without any preexisting condition which could explain the positive screening (i.e. a history of hayfever which likely explains sneezing or a report of physical activity which likely explains muscle soreness), you will be referred to your primary care physician for follow-up and further testing.

Additional Information:
While the results from the COVID-19 test will be provided to you, results from the surveys will not be shared with you.

Your de-identified private information (private information with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data.**

The nasal swab, saliva, tongue swab, and blood specimens if obtained from you for this research, which may or may not include your identifiable private information, will not be maintained nor used for commercial profit.

DHCW LAB participants' saliva and tongue samples will be sent to the Department of Oral Biology, Rutgers School of Dental Medicine and/or Genomics Laboratory, New Jersey Medicine School, and your blood sample will be sent to the Rutgers PHRI lab for Processing.

DHCW POC participants' blood samples will be sent to the Rutgers PHRI lab for Processing.

Risks and Discomforts

This research involves a tongue swab procedure with minimal risk to you as a DHCW LAB participant. The tongue swab involves rolling a small circular brush on the tongue to collect epithelial cells which may cause slight discomfort to you.

This research involves the nasal swab POC testing procedure with minimal risk for you as a DHCW POC participant. The nasal swab involves insertion of a swab into the forward part of the nasal cavity by a member of the healthcare team, which may cause slight discomfort to you.

This research also involves a finger prick to obtain a blood sample with minimal risk. A finger prick test is a procedure in which a finger is pricked with a lancet to obtain a small quantity of capillary blood for testing. The site where the blood is to be collected is sterilized with a topical germicide, and the skin is pierced with a sterile lancet. There is a slight risk of discomfort from the lancet stick and irritation or infection in the area the where the lancet punctures the skin.

As COVID-19 tests are not 100% accurate, if you test negative, you may gain a false sense of security. It is important that you continue to wear you mask when around other people and continue to social distance. If you test positive, you will be directed to see you personnel physician or we can refer you to a physician for further instructions.

The most common risk for participating in this study is a possible breach of confidentiality.

Benefits

The benefits of taking part in this study will be receiving free COVID-19 testing and gaining knowledge of your likely COVID-19 status. However, it is possible that you may not receive any direct benefit from taking part in this study.

Alternatives

You do not have to take part in this study if you don't want to, it is your choice. Not participating will not affect your status as an employee with the participating dental office.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The University of Alabama at Birmingham and the University of Rochester Institutional Review Boards (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.

- National Institutes of Health
- The Office for Human Research Protections (OHRP)
- National Dental Practice-Based Research Network Administrative and Resource Center (University of Alabama at Birmingham)
- National Coordinating Center for the National Dental Practice-Based Research Network (Kaiser Permanente Center for Health Research)
- Rutgers School of Dental Medicine
- University of Rochester Eastman Institute for Oral Health

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A designated National Dental PBRN dentist member of the practice, known as the PBRN Practitioner, will be responsible to notify test results to each participating Dental Health Care Worker in the practice in a confidential manner.

As part of this study, you will be tested for COVID-19. If the results show that you are positive for COVID-19, the study staff will tell you the results. The study staff will be required to give your name to the state's Department of Public Health if you test positive because this is the law.

Voluntary Participation and Withdrawal

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are

entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you decide to withdraw your consent for data already collected, it must be done in writing. Please send the letter to Dr. Cecile Feldman, Rutgers School of Dental Medicine, 110 Bergen Street, Room B815, Newark, NJ 07103.

If you withdraw your consent, the National Dental PBRN Node Coordinator will contact you to discuss the reason for your withdrawal. If you are an employee, taking part in this research is not part of your work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your job. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation
You will receive a $125 check for participation in this study.

New Findings
You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions
If you have questions about taking part in this study you can contact the Principal Investigator: Cecile A. Feldman, DMD, Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ 07045, (973) 972-4634.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Participant Name

_____

Signature of Participant Date

_____

Participant Email Address

CONSENT FORM TO BE PART OF A RESEARCH STUDY: PATIENTS

Title of Research: Pragmatic Return to Effective Dental Infection Control through Triage and Testing (PREDICT) PBRN Feasibility Study

UAB IRB Protocol #: **IRB-300007026**

Principal Investigators: Cecile Feldman, DMD, MBA

Sponsor: National Institutes of Health

General Information	You are being asked to take part in a research study because you are scheduled for a dental visit. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to refine protocols and logistics developed for performing screening and COVID-19 testing in dental offices.
Duration & Visits	You will be in this study over a 2-3 week period. Your total active participation will be approximately 1 hour.
Overview of Procedures	Two weeks before your routine dental visit, you will be asked to complete a survey. Some participants, one week before their routine dental visit will be asked to submit saliva for a COVID-19 test. Some participants, at the beginning of their dental visit, an in-office COVID-19 test will be performed. At the beginning of your dental visit, you will undergo a COVID-19 triage screening and at the end of your dental visit, you will complete two electronic surveys.
Risks	The most common risk for participating in this study is a possible breach of confidentiality. This research involves the nasal swab testing procedure. The nasal swab involves insertion of a swab into the forward part of the nasal cavity by a member of the healthcare team which may cause slight discomfort to you.
Benefits	The benefits of taking part in this study will be receiving free COVID-19 testing and gaining knowledge of your likely COVID-19 status.
Alternatives	Being in this research study is voluntary. You do not have to take part in this study if you don't want to, it is your choice. Not participating will not affect your care as a patient of record with your dentist.

Purpose of the Research Study

We are asking you to take part in a research study. The COVID-19 pandemic has created serious concerns about the return of patients and dental professionals to a dental office. This study is being done to test out methods to be followed in a large scale, multi-practice, clinical study focused on improving the safety of the dental office by improving triage procedures and developing standard COVID-19 testing protocols. Approximately 40 patient subjects are being asked to take part in this study.

Study Participation & Procedures

- If you agree to take part in this study, participants will be split into 2 groups called Patient LAB and Patient Point of Care (POC). Each group will have slightly different procedures. Participants will participate in the LAB or POC protocol based upon the preference of your office's Practice Based Research Network dentist. Two weeks before your routine dental appointment, you will receive and complete a baseline questionnaire. Questions may explore perceptions of safety and comfort, reasons for delaying dental care, concerns about returning to dental care, safety precautions valued, importance of triage and testing, and demographics. It will take approximately 10 minutes to complete the questionnaire. The questionnaire will be sent electronically and you can complete the questionnaire on any personal device, including a computer, tablet or telephone.

- LAB participant, approximately one to two weeks before your routine dental appointment, a COVID-19 saliva specimen test kit will be mailed to your home. One week before your routine dental visit, you will be asked to complete the COVID-19 saliva test, which involves spitting in a tube following manufacturer directions on the package insert, package as directed, and drop off the completed test kit at your dentist's office. It will take approximately 15 minutes to complete the COVID-19 saliva test. Travel time to the dental office will vary and is estimated at 15-45 minutes.

  It will take approximately 5 minutes for the phone screening.

- When you arrive to the dental office for your appointment, you will undergo a an in-office COVID-19 triage screening which includes the series of symptom questions along with a temperature check and pulse oximeter reading. You will be asked whether or not you currently have:
  - fever or chills
  - cough
  - shortness of breath or difficulty breathing
  - fatigue
  - muscle and body aches
  - headache
  - loss of taste
  - loss of smell
  - sore throat
  - congestion or runny nose
  - nausea or vomiting
  - diarrhea

- It will take approximately 5 minutes for the in-office triage.

- POC participant, will complete a COVID-19 Point of Care (POC) test, during which the dental practitioner will sweep the inside of your nose using a nasal swab to collect your specimen for the COVID-19 test. The dental practitioner will process the sample in the office and give you the results within 15 minutes. In total, it will take approximately 20 minutes to complete COVID-19 POC test.

- After your routine dental visit, you will complete two additional questionnaires. For the *Patient End-of-Visit Survey*, questions explore perceptions with testing preferences, PPE observed, environmental controls observed, concerns about returning to dental care, safety precautions valued, importance of triage and testing, likelihood of reporting symptoms, dentist's role in COVID-19 testing and vaccinations. For the *Patient Participation Survey*, questions explore perceptions related to study participation including survey and testing logistics. It will take approximately 15 minutes to complete both surveys electronically on a tablet provided by the dental office.

Reportable Diseases:
If you have a negative COVID-19 test, your dental visit will take place as scheduled. If you have a positive COVID-19 test, your dental visit may be rescheduled and you will be referred to your primary care provider for follow-up.

Additional Information:
While the results from the COVID-19 test will be provided to you, results from the surveys will not be shared with you.

Your de-identified private information (private information with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data.**

As a LAB participant, the saliva specimen obtained from you for this research, which may or may not include your identifiable private information, will not be maintained nor used for commercial profit.

As a POC participant, the nasal swab specimen obtained from you for this research, which may or may not include your identifiable private information, will not be maintained nor used for commercial profit.

Risks and Discomforts
As a POC participant, this research involves the nasal swab POC testing procedure with minimal risk. The nasal swab involves insertion of a swab into the forward part of the nasal cavity by a member of the healthcare team which may cause slight discomfort to you.

As COVID-19 tests are not 100% accurate, if you test negative, you may gain a false sense of security. It is important that you continue to wear you mask when around other people and continue to social distance. If you test positive, you will be directed to see you personnel physician or we can refer you to a physician for further instructions.

The most common risk for you participating in this study is a possible breach of confidentiality.

Benefits
The benefits of taking part in this study will be receiving free COVID-19 testing and gaining knowledge of your likely COVID-19 status. However, it is possible that you may not receive any direct benefit from taking part in this study.

Alternatives
You do not have to take part in this study if you don't want to, it is your choice. Not participating will not affect your care as a patient of record with your dentist.

Confidentiality
Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The University of Alabama at Birmingham and the University of Rochester Institutional Review Boards (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes of Health
- The Office for Human Research Protections (OHRP)

- National Dental Practice-Based Research Network Administrative and Resource Center (University of Alabama at Birmingham)
- National Coordinating Center for the National Dental Practice-Based Research Network (Kaiser Permanente Center for Health Research)
- Rutgers School of Dental Medicine
- University of Rochester Eastman Institute for Oral Health

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

As part of this study, you will be tested for COVID-19. If the results show that you are positive for COVID-19, the study staff will tell you the results. The study staff will be required to give your name to the state's Department of Public Health if you test positive because this is the law.

Voluntary Participation and Withdrawal

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you decide to withdraw your consent for data already collected, it must be done in writing. Please send the letter to Dr. Cecile Feldman, Rutgers School of Dental Medicine, 110 Bergen Street, Room B815, Newark, NJ 07103.

If you withdraw your consent, the National Dental PBRN Node Coordinator will contact you to discuss the reason for your withdrawal.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation
As a LAB participant, you will receive a $100 check for participation in this study. As a POC participant, you will receive a $50 check for participation in this study.

New Findings
You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions
If you have questions about taking part in this study you can contact the Principal Investigator: Cecile A. Feldman, DMD, Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ 07045, (973) 972-4634.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Participant Name

_____

Signature of Participant Date

_____

Participant Email Address