Pragmatic Return to Effective Dental Infection Control through Triage and Testing (PREDICT) Rutgers Single Site Point-of-Care (POC) Patient Subjects

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Principal Investigator: Cecile A. Feldman, DMD, MBA

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NIDCR Program Oficial: Dena Fischer, DDS, MSD, MS

NIDCR Medical Monitor: N/A

RUTGERS
School of Dental Medicine

Office of the Dean
Rutgers, The State University of New Jersey
110 Bergen Street
Newark, NJ 07101

feldman@rutgers.edu

p. 973-972-4634
f. 973-972-3689

Cecile A. Feldman, DMD, MBA
Dean

CONSENT TO TAKE PART IN A RESEARCH STUDY
Patient Consent Form
Point-of-Care Protocol

Title of Study: Pragmatic Return to Effective Dental Infection Control through Triage and Testing (PREDICT) - Rutgers Single Site

Principal Investigator: Cecile A. Feldman, DMD, MBA

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to refine protocols and logistics developed for performing screening and COVID-19 testing in dental offices. If you take part in the research, you will be asked to complete to complete a survey before you dental visit, a survey after your dental visit performed, and have a COVID-19 test and screening performed. Your time in the study will take about 2 hours over 1-2 week period.

Possible harms or burdens of taking part in the study may be some discomfort from the screening procedure and/or a false sense of security if you have a negative result. Possible benefits of taking part may be learning about your COVID-19 status.

An alternative to taking part in the research study is not taking part in the research study.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Cecile Feldman, DMD, MBA is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Feldman may be reached at Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ 07103. Her phone number is (973) 972-4634.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

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.

Who may take part in this study and who may not?
Anyone who is 18 years of age or older, who is able to understand and sign the consent form and is scheduled for a dental office visit can participate in this study.

Who may not take part in this study?
Anyone who has previously participated in the feasibility study and anyone who is unwilling to have their de-identified data released to other researchers cannot participate in the study.

Why have I been asked to take part in this study?
You have been asked to participate because you are scheduled for a dental visit.

How long will the study take and how many subjects will take part?
Twenty subjects are being asked to take part in this study. It will take about 30 minutes to answer some survey questions and about 15 minutes to have the COVD-19 test done. You will be asked to come to your appointment 30 minutes early so the nasal swab can be completed.

What will I be asked to do if I take part in this study?
You will be asked to do the following:

- Week before Dental Visit
  - Complete an electronic consent
  - Complete a survey: *Patient Pre-Visit Survey*
- Evening before Dental Visit
  - Undergo a COVID-19 triage screening over the phone
    - Screening includes questions
- At the start of the Dental Visit
  - Undergo a COVID-19 triage screening in the office
    - Screening includes questions, temperature check, and pulse oximeter reading
  - Complete COVID-19 POC test
    - A nasal swab will sweep the inside of your nose to collect your specimen for the COVID-19 test
- At the End of the Dental Visit
  - Complete two surveys
    - *Patient End-of-Visit Survey*
    - *Patient Participation Survey*

Once the study is completed, the collected data will be made available to other researchers. All data, including yours will be de-identified.

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 will be rescheduled. You will be referred to your primary care provider for follow-up.

What are the risks of harm or discomforts I might experience if I take part in this study?
If you have having the saliva COVID-19 test, there are no harms or discomforts which are anticipated. If you are having the nasal swab COVID-19 test, you may experience some irritation in your nose but this discomfort should quickly dissipate.

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.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may 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.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
Results from the surveys will not be provided but the results from the COVID-19 test will be provided

Will there be any cost to me to take part in this study?
There will be no costs for you to take part in this study.

Will I be paid to take part in this study?
You will receive a $50 check to take part in this study.

How will information about me be kept private or confidential?
A link will be maintained between identified and de-identifiable data. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information or biospecimens collected for this research after the study is over?

- The nasal swab collected from you for this research will not be used by or distributed to investigators for other research.
- De-identified data will be sent to the National Institute for Dental and Cranial Facial Research (NIDCR) Dental Practice Based Research Network (PBRN) Network Coordinating Center.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Cecile A. Feldman, DMD, Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ, 07045.

Any data that has already been sent to NIDCR PBRN Network Coordinating Center cannot be withdrawn because there may not be any identifiers with the data.

Who can I contact if I have questions?

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Cecile A. Feldman, DMD, Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ 07045, (973) 972-4634.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: Newark HealthSci IRB, 65 Bergen St., SSB 511, Newark, NJ 07107, (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-1149, email us at humansubjects@ored.rutgers.edu or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- COVID-Triage responses
- Research Survey responses

- COVID-19 test results

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- National Institutes of Health
- Dental Practice Based Research Network Coordinating Center
- New Jersey Department of Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Cecile A. Feldman, DMD, Rutgers School of Dental Medicine, 110 Bergen Street, Newark, NJ 07103.

How Long Will My Permission Last?
There is no set date when your permission will end. Your health information may be studied for many years. The link between identified and de-identified data will be maintained for six years after study completion.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____Date: _____