Pragmatic Return to Effective Dental Infection Control through Triage and Testing

(PREDICT)

PBRN Feasibility Study

NIDCR Protocol Number: 20-067-E

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NIDCR Medical Monitor: N/A

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STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Council for Harmonisation guidelines for Good Clinical Practice (GCP) (ICH E6) and the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46). National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
1.01	7/25/21	Added revision history table; doubled enrollment to account for not all consented individuals will go on to complete the protocol; added Abbot BinaxNOW Covid-19 Ag Card and COVID-19 Antigen SelfTEST as POC tests; added collection of tongue cells for PCR testing; removed duplicate patient consent; added activities occurring with designated window as outcome measures; removed patient triage the night prior to visit; specified event performed outside of a window is not considered a protocol deviation; clarified nasal, tongue cell and capillary blood specimen collection to self-collection for the PBRN member and by the PBRN practitioner or his/her designee for other DHCWs and the patient subjects; changed UPS package drop-off to be at UPS store or drop box rather than the dental office; removed eligibility requirement that a DHCW have a smart phone; added eligibility requirement that patient subjects have access to a computer or electronic tablet with internet connection and that they be computer literate enough to be able to complete the consent and survey questionnaires; updated event reporting table

SIGNATURE PAGE

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

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LIST OF ABBREVIATIONS

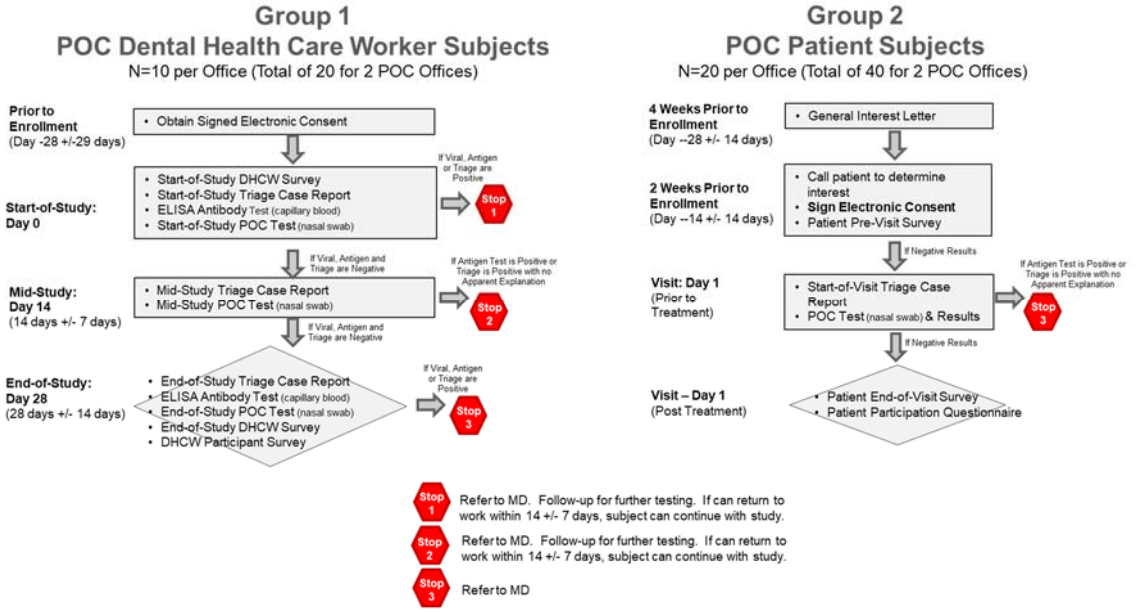
AE	Adverse Event/Adverse Experience
PBRN	Practice Based Research Network
CFR	Code of Federal Regulations
CSI	Clinical Site Investigator
CIOMS	Council for International Organizations of Medical Sciences
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRO	Contract Research Organization
DCC	Data Coordinating Center
DHCW	Dental Health Care Workers
DHHS	Department of Health and Human Services
DMFS	Decayed, missing, and filled tooth surfaces
DSMB	Data and Safety Monitoring Board
eCRF	Electronic Case Report Form
FDA	Food and Drug Administration
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISM	Independent Safety Monitor
LAB	Laboratory Based Saliva-Based COVID-19 Test
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator

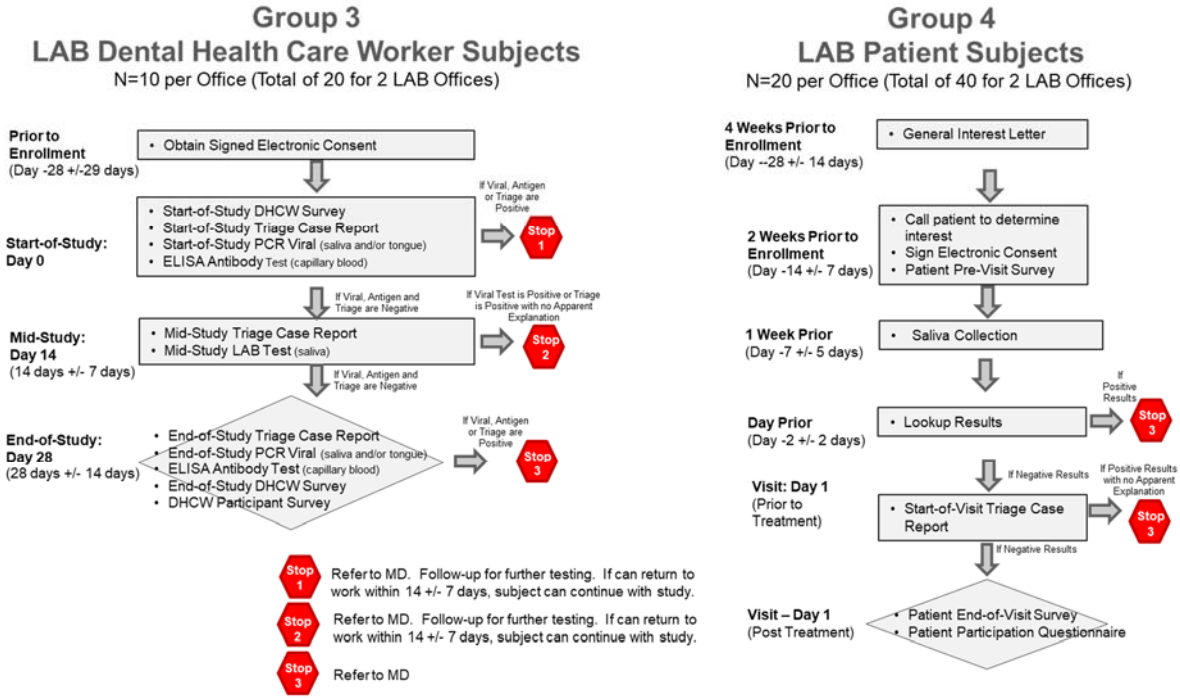
PO	Program Official, NIDCR, NIH
POC	Point-of-Care COVID-19 Test
PREDICT	Pragmatic Return to Effective Dental Infection Control through Triage and Testing
PS	Project Scientist, NIDCR, NIH
QA	Quality Assurance
QC	Quality Control
QoL	Quality of Life
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States
WHO	World Health Organization

PROTOCOL SUMMARY

Title:	Pragmatic Return to Effective Dental Infection Control through Triage and Testing: PBRN Feasibly Study
Précis:	We will conduct a feasibility study to develop and assess procedures for improved COVID-19 triage and testing in dental practices to increase safety and perceptions of safety of Dental Health Care Workers (DHCWs) and their patients. Four National Dental Practice-Based Research Network (PBRN) member dentists and their office staff will be recruited to participate as either as a Point of Care (POC) Office or a LAB office based upon preference of the PBRN member dentist. . In the POC offices, we will test out procedures for POC/SARS-CoV-2 antigen testing in DHCWs and patients of the practice along with enhanced triage using pulse oximeters. In the LAB offices, DHCWs and patients will test procedures for a saliva-based laboratory SARS-CoV-2 viral test (LAB) along with enhanced triage methods. Based on office recruitment (POC or LAB), viral, antigen and/or antibody COVID-19 tests will be administered to DCHW and patients entering the dental office. In addition, the use of pulse oximeters will be added to the DHCW and patient triage protocol. The feasibility of implementing COVID-related testing and enhanced triage procedures in the dental setting will provide preliminary data to inform a larger network-wide study grant application.
Objectives:	**Primary:** The primary objective of this study is to assess the feasibility of procedures for both COVID-19 point-of-care and lab-based testing along with enhanced triage in dental offices.
Population:	This study will take place in dental offices, each of which with at least one National Dental PBRN member dentist. DHCWs working in a dental office with a participating National Dental PBRN dentist and their adult patients 18 years old and older will be recruited to participate. In each office, up to 10 DHCWs (dentists, hygienists, assistants and office staff) including the PBRN member dentists and up to twenty (20) patients will be enrolled. In total, up to forty (40) DHCW (dentists, hygienists, assistants and office staff will be enrolled) and eighty (80) patients enrolled.
Number of Sites:	Four (4) National Dental PBRN offices
Study Duration:	Twelve (12) months
Subject Participation Duration:	DHCWs in both POC offices and LAB offices will participate in the study for 1 month. Patients being seen in POC or LAB offices will participate in the study for approximately two (2) weeks.
Estimated Time to Complete Enrollment:	Six (6) months

Schematic of Study Design





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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Description of Problem:

The COVID-19 pandemic: COVID-19 has created serious concerns about the safety of patients and dental professionals as they return to a practice environment. The spread of this ubiquitous virus was first thought to be through droplets but soon it became clear that the virus could be spread by aerosols [5,6]. Many dental procedures require the mechanical preparation of hard and soft tissue using high speed handpieces which are water cooled and generate significant aerosolized sprays. The extent to which dentally-generated aerosols linger within operatories has not been clearly tested but it is certain that clinic dental personnel will be exposed to significant aerosol sprays derived from patients' oral cavities [7]. As we learn more about COVID-19 and viral transmission we understand that infection and spread of the virus is due to the viral load (or dose) and the time of contact [8,9].

Uniqueness of Dental Practice: Unlike many procedures in medicine, dental/patient contact is eye to eye with close proximity between patient and dental professionals [10]. Furthermore, a dental procedure can often take as long as 1 hour and prolonged close contact between dentist and patient is inevitable. Despite personal protective equipment (PPE) that includes N95 masks, face shields, gowns, and high-speed suction, viral spread from infected patients is likely in the dental setting. This suggests that the only safe solution for maintaining the health and safety of dental professionals in the time of COVID-19 is removing virus-infected patients from their offices [11].

Waiting Rooms and Airflow: Obvious issues confronting dental practices have been discussed, however, waiting rooms with patients, bathrooms and passageways are all additional areas within offices that can be of safety concern. Further, the airflow in confined office spaces where patients can be waiting for 30 minutes or more can be hazardous if an asymptomatic but COVID-19 infected patient is in close proximity to a susceptible patient. Patients in a dental office can be at risk for infection that can have varied presentation and severity and may be life threatening especially in patients with pre-existing conditions [21-23].

Solutions: One way of providing the security that dental offices are safe for both the dental professional and patient is by taking measures to prevent anyone who harbors the COVID-19 virus from entering the office. This of course would necessitate testing every patient at every visit or by establishing the fact that patients are safe if they have neutralizing antibody to the COVID-19 virus. These solutions, at this moment, appear to be impractical particularly if the virus affects a very small percentage of the population, testing is inaccurate, and obtaining testing results is not immediate. A solution to this problem is imperative both for the safety and security of the patient and dental professional. But what's to be done? How do we achieve our goal of providing a safe and secure environment that allows for routine dental care?

Several challenges exist to routine and comprehensive testing: The costs, turnaround time (maximum practical utility would perhaps be derived from a simple, rapid, accurate, inexpensive point-of-care test that is not technically demanding, and such a test has not yet been validated). This proposal compares the use of one such candidate POC test with the current screening gold-standard.

Conclusions*:* With each day, patients are not receiving dental services because of a COVID-19 transmission concern. Understanding risk associated with COVID-19 transmission in a dental practice and the effective use of testing and other practice modifications could dramatically reduce the risk, facilitating dental health care providers and patients to be comfortable with seeking/providing essential dental services. This proposal is designed to develop procedures that address this serious problem and test the feasibility of these procedures in a pragmatic manner to address this existing insurmountable problem that can affect the future of dental practice and the dental health we have come to expect.

2.2 Rationale

Typical dental protocols recommend twice yearly visits to dentists for prevention and maintenance of oral health [12,13]. Dental patients who may be asymptomatic for medical conditions are seen routinely in dental offices and can be screened for the early phases of medical disease during routine dental visits. For example, blood pressure monitoring and simple blood test for glycosylated hemoglobin (HbA1c) levels can be performed in dental offices, with referral to medical personnel for further assessment [18,19]. This medical screening can be considered as value-added should dental health professionals provide augmented diagnostic benefit to patients who are unaware of their need for medical intervention. However, in this time of uncertainty dentistry has been impacted by fear and poorly defined strategies to mitigate COVID-19, that can compromise the willingness of dental professionals to open their dental practices [20].

Little is Known Regarding the Effectiveness COVID-19 Triage in Dental Practice*:* Little is known about the effectiveness of triage protocols which have been recommended by the CDC. For example, most offices are using temporal thermometers, yet many are uncalibrated. In addition, screening questions continue to evolve, and the veracity of patient responses remains unverified.

Little is Known Regarding the Impact of COVID-19 Testing in Dental Practice: Little is known about the value of testing and about the willingness of dental health care workers (DHCW) to implement COVID-19 testing in a dental office, who would pay for the testing, or the most effective use of such testing.

The following questions need to be answered:

- Perception of safety and comfort: Will patients and DHCW in an office with either LAB or POC testing feel safer and be more comfortable delivering/receiving care during a COVID-19 or other infectious disease pandemic?
- Testing preference: Do DHCW and patients prefer POC testing rather than testing that requires laboratory processing?
- Effectiveness of triage: Is the triage protocol being followed today effective or do patients and DHCW respond negatively to COVID-19 symptoms because of the fear of not being seen or being turned away from work?
- Effectiveness of triage methods: Are objective measures such as temperature and pulse oximeter readings effective in identifying “asymptomatic” cases?

2.2.1 Potential Risks

This research involves testing procedures with varying degrees of risk to the study participants.

- Saliva Test- minimal risk. The saliva test is non-invasive, requires spitting into a tube, and is completed independently, without interaction with a member of the healthcare team.
- Nasal swab- minimal risk. The nasal swab involves insertion of a swab into the forward part of the nasal cavity (not beyond the nares) by a member of the healthcare team which may cause slight discomfort to the participant.
- Tongue swab – minimal risk. The tongue swab involves rolling a small circular brush on the tongue to collect epithelial cells which may cause slight discomfort to the participant.
- Finger prick- 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.

In addition, different COVID-19 test types have varying degrees of sensitivity and specificity, which may result in false negative and false positive test results. A false negative result may give a participant a false sense of security, and the patient would have been treated with each office’s infection control protocol

regardless of participation in the study. Regardless, false negative test results may pose additional viral transmission risk to DHCW who interact with and treat the patient, and other individuals who come into contact with the asymptomatic but infected patient. On the other hand, a false positive result will prompt the DHCW or patient to undergo additional testing by their primary health care provider and may cause additional anxiety. Should they test positive again, they would need to follow their local health department recommendations which may require quarantine.

There is a risk of loss of confidentiality for all study participants. Precautions will be in place to minimize this risk, such as collecting only minimal identifying information, using unique study codes for participants, collecting data using encrypted computers, and maintaining electronic data files on a password-protected computer drive, and storing data on encrypted computers or in locked cabinets (located in locked offices). Individual identifier numbers that are linked to participant contact information will be stored separately from the data. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.

2.2.2 Potential Benefits

There is no benefit to DHCW and patients participating in this study beyond the fact that DHCW and patients would receive the results of the COVID-19 tests they undergo.

3 OBJECTIVES AND OUTCOME MEASURES

3.0 Feasibility Study Outcomes

Objectives	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To Determine DHCW and Patient Willingness to Participate	Willingness to participate is important in determining whether dental offices, DHCW and patients would be willing to participate in a large-scale study	• Ratio of DHCW agreeing to participate as compared to all DHCW asked to participate • Ratio of patients agreeing to participate as compared to all patients asked to participate • Thoroughness of consent process and ability to ask questions	***Willingness to Participate:*** • DHCW – at time of consent by DHCW consent • Patients – at time of consent by patients
To Determine DHCW and Patient Willingness/Ability to Follow Thru with Triage, Testing and Survey Administration Procedures	Determining willingness and ability to follow thru with triage, testing and survey administration procedures is important for refining the survey procedures	**For both DHCW and Patients** • % who complete the study • % who complete surveys o Start-of-Study DHCW Survey o End-Of-Study DHCW Survey o Pre-Visit Patient Survey o End-of-Visit Patient Survey • % activities occurring within the defined window o Consents o Start-of-Study DHCW Survey, Triage and Testing o End-Of-Study DHCW Survey, Triage and Testing o Mid-Study Triage Testing o Pre-Visit Patient Survey o End-of-Visit Patient Survey o Patient Testing • % who feel testing (Saliva, PCR, POC, and ELISA Antibody) procedure was easy to comply with o Specimen collection o Specimen preparation for shipping o Specimen storage o Timeliness of results o Reporting of results	***% Complete Study:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1) ***% All Surveys Completed:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1) ***% Activities Occurring within the defined window:*** • For DHCW – Consent, Start-of-Study Visit, Mid-Visit, End-of-Study Visit • Patients – Consent, LAB material receipt, LAB specimen sent to laboratory, LAB results, Treatment Visit ***% Feel Testing Protocol was Easy to Comply With:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1)

Objectives	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To Determine Ease of Use with REDCap Survey Instruments • Dental Health Care Worker Subject o Start-of-Study Survey o End-of-Study Survey o Triage Survey • Patient Subject o Start-of-Visit Survey o End-of-Visit Survey o Triage Survey	Determining the ease of use and completeness of the REDCap instruments enables refinement of the system	**For both DHCW and Patients** • % who feel surveys are easy to complete due to administration method: o Start-of-Study DHCW Survey o End-of-Study DHCW Survey o Pre-Visit Patient Survey o End-of-Visit Patient Survey o Triage Case Report • % who feel survey questions were understandable: o Start-of-Study DHCW Survey o End-of-Study DHCW Survey o Pre-Visit Patient Survey o End-of-Visit Patient Survey o Triage Case Report • % completed surveys: o Start-of-Study DHCW Survey o End-of-Study DHCW Survey o Pre-Visit Patient Survey o End-of-Visit Patient Survey o Triage Case Report	***% indicating surveys were easy to complete due to administration method:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1) ***% indicating survey questions were easy to understand:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1) ***% Surveys Completed:*** • For DHCW - At time End-of-Study (Day 28) • Patients – End-Of-Visit (Day 1)

3.1 Primary Outcomes for Full Study (Data Collection is Being Performed to Determine Instrument Feasibility)

Full Study Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
Objective 1 – Dental health care personnel feel safe in the dental office	***Safety Culture Evaluation Survey*** for DHCW is a 6-item survey using a 4 point Likert scale seeking the agreement with 6 criteria associated high performing safety organization characteristics. ***Willingness to Come to Work*** reflects a DHCW's safety in the workplace. ***Willingness to Refer Other Patients*** reflects DHCW's safety of the dental practice.	***DHCW - Safety Culture Evaluation Survey:*** 6 item survey. Numeric responses to each item using a four-point Likert Scale are summed for a score which reflects the level of safety in the organization. (1=strongly agree, 2=agree, 3=disagree, 4=strongly disagree.) ***DHCW- Safety:*** How safe to do feel coming to work? 5 Point Likert scale ***DHCW Willingness to Refer Other Patients:*** How likely would you refer a family or friend to this dental office? 5 Point Likert Scale	***Sense of Safety for Dental Health Personnel:*** • Start of study • End of study ***Willingness to Refer Other Patients:*** • DHCW – Start of study • DHCW – End of study

3.2 Secondary Outcomes for Full Study (Data Collection is Being Performed to Determine Instrument Feasibility)

Objective	Brief Description/ Justification of Outcome Measure	Outcome Measured By	Time Frame
Objective 2: Determine the Efficiency and Effectiveness of: • **Efficiency of DHCW Triage Protocols** • **Efficiency of Patient Triage Protocols** • **Effectiveness Patient Testing Protocols**	***Efficiency of Triage Protocols:*** • Acceptability of triage protocols is based upon resources (time and effort and facilities) required to implement the protocol ***Effectiveness of Triage Protocols*** • Dentist's willingness to continue use of triage protocols is based upon the usefulness/outcomes of the triage. ***Efficiency of Testing Protocols:*** • Acceptability of testing protocols is based upon resources (time and effort and facilities) required to implement the protocol ***Effectiveness of Testing Protocols*** • Dentist's willingness to implement testing protocols is likely to be based upon testing's ability to identify asymptomatic DHCW and patients.	***Efficiency of Triage Protocols:*** • Time needed to complete triage survey ***Effectiveness of Triage Protocols*** • Comparison of number of DHCW not able to report to work due to LAB or POC test results • Comparison of Triage Survey to Medical History consistent with COVID-19 symptoms for DHCW ***Efficiency of Testing Protocols:*** • Time and supplies needed to conduct LAB vs. POC test ***Effectiveness of Testing Protocols*** • Comparison of number of DHCW not able to report to work • Comparison of number of patients not able to report for their patient visits	***Efficiency of Triage Protocols:*** • End of study ***Effectiveness of Triage Protocols*** • End of study ***Efficiency of Testing Protocols:*** • End-of-Study ***Effectiveness of Testing Protocols*** • End-of-Study

3.3 Tertiary/Exploratory Outcomes for Full Study (Data Collection is Being Performed to Determine Instrument Feasibility)

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
Objective 3 (exploratory): Examine SARS-CoV-2 Positivity Rate and Immuno-Conversion Rate • **DHCW positivity rate** • **DHCWs with IgG** • **DHCWs with IgM** • **DHCWs who immune-convert**	***Positivity Rate:*** • POC antigen with a nasal swab • PCR with a saliva or tongue scraping specimen ***Immuno-conversion Rate*** • ELISA with Capillary Blood specimen	***DHCW Positivity Rate:*** • POC antigen • PCR viral test ***DHCW Immuno-conversion Rate*** • ELISA antibody	***DHCW Positivity Rate:*** • Start of Study • Every 2 weeks • End of Study ***DHCW Immuno-conversion Rate*** • Start-of-Study • Every 2 Weeks • End-of-Study

4 STUDY DESIGN

Description: This observational study will assess the feasibility of implementing COVID-related testing and triage procedures in the dental setting to ensure the safety of DHCWs and patients. Results from this study may provide preliminary data to inform a larger network-wide study grant application.

This study will be conducted in four (4) private practice dental offices, each of which with at least one National Dental Practice Based Research Network (PBRN) member dentist. Based upon preference of the Practice Based Research Network dentist, offices will participate as either a Point of Care (POC) Office (2 offices) or a LAB office (2 offices). In the POC offices, we will test procedures for POC/SARS-CoV-2 antigen testing in DHCWs and patients of the practice along with enhanced triage using pulse oximeters. In the LAB offices, DHCWs and patients will test procedures for a saliva-based laboratory SARS-CoV-2 viral test (LAB) along with enhanced triage methods. The National Dental PBRN dentist and office will choose to participate in either the POC or LAB group; offices will not be assigned to study groups.

Study Population: The study population for this study will be all dentists, hygienists, dental assistants and dental office personnel (e.g., dentists, hygienists, dental assistants, front office staff) working in a participating dental office, as well as patients being treated in the participating dental office.

Important Outcomes: For this study, important outcomes include percent of both DHCW and patients willing to participate percent completing the protocol. See Section 3 for more detail.

Number of Study Groups: Four **(4)**

1. DHCW in POC Offices
2. Patients in POC Offices
3. DHCW in Lab Offices
4. Patients in Lab Offices

Expected Duration of Subject Participation:

DHCWs (in POC or LAB Offices) - 1 month
Patients (in POC or LAB Offices) - 2 weeks

Sequence of Procedures and Duration of Study Period: See Section 7.

5 STUDY POPULATION

5.1 Participant Inclusion Criteria

A ***Dental Health Care Worker*** must meet all of the following criteria to be eligible to participate in the study:

- Be 18 years or older
- Be a National Dental PBRN member dentist or work in a dental office with a National Dental PBRN member dentist who consents to study participation
- Be able to understand the informed consent.
- Provide signed and dated informed consent form
- Be able to understand all instructions for data collection instruments
- Be willing and able to comply with all study procedures, including COVID-19 testing, and be available for the duration of the study

A ***Patient*** must meet all of the following criteria to be eligible to participate in the study:

- Be 18 years or older
- Be able to understand the informed consent.
- Have a computer or electronic tablet with internet access
- Able to complete consent and questionnaire on a computer or electronic tablet
- Provide signed and dated informed consent form
- Be able to understand all instructions for data collection instruments
- Be willing and able to comply with all study procedures, including having a COVID-19 test performed

5.2 Participant Exclusion Criteria

Participants would be excluded if they participated in the feasibility study previously conducted at Rutgers University.

5.3 Strategies for Recruitment and Retention

Target Sample Size: 40 dental care health workers and 80 patients.

Target Sample Size by Gender, Race, Ethnicity, and Age: Study population will be drawn from National Dental PBRN dentist members, their co-workers and patients seen in their office. Any adult 18 years and older meeting the inclusion criteria and not meeting any exclusion criteria will be eligible to participate. It is expected that the mix of gender, race and ethnicity will reflect the patient mix of the participating dental offices.

Study Population: The DHCW study population will be dentists, hygienists, assistants and office staff who work in an office with a National Dental PBRN member dentist. The patient study population will be drawn from the dental practice with the National Dental PBRN member dentist.

Inclusion of Women and Minorities and Individuals of All Ages:

Women: Women will be included in this study.
Minorities: Minorities will be included in this study.

Recruitment Strategies: Four (4) National Dental PBRN practitioners who have 4 or more DHCW in their office will be recruited to participate by the National Dental PBRN Node Coordinator. The Node Coordinator will then recruit DHCWs within the practice to participate. If a practice is unable to consent at least 5 DHCWs, the practice will not participate in the study. Another National Dental PBRN practice will be recruited to participate.

Patients will be sent a letter about 4 weeks prior introducing the study by the PBRN practitioner. The PBRN practitioner or PBRN investigators in the office will reach out to patients by phone about 2 weeks prior to the dental visit. The study will be explained and if the patient is interested, an e-mail link will be sent which will allow the patient to review the informed consent. A phone number will be provided to answer questions.

Recruitment Protocol (All Study Groups):

The PRBN Node Research Coordinator will recruit PBRN dentist members to participate in the protocol. The PBRN Node Research Coordinator will contact PBRN dentist members to introduce the study and gauge initial interest. The dental office will be enlisted if the PBRN dentist member and 4-9 additional office DHCWs of the practice are willing to participate and the PBRN member is willing to perform the responsibilities of the protocol including enrolling and completing 10 patients. The PBRN practitioner's preference will determine which protocol (POC or LAB) will be followed in the office. In total, two POC offices will participate, and two LAB offices will participate.

Office	Study Group	Protocol	COVID-19 Related Tests (Method)
POC	1- DHCW in POC Offices	POC DHCW Protocol	• Antigen (nasal swab) • Antibody (capillary blood)
	2- Patients in POC Offices	POC Patient Protocol	• Antigen (nasal swab)
LAB	3- DHCW in Lab Offices	LAB DHCW Protocol	• Virus (saliva and/or tongue) • Antibody (capillary blood)
	4- Patients in LAB Offices	LAB Patient Protocol	• Virus (saliva)

Retention: In order to minimize loss of study participants and/or incomplete data collection, the following activities will take place:

- Node Coordinators will work with National Dental PBRN study participants responsible for recruiting subjects and completing surveys to encourage patient enrollment and study completion.
- Participants will receive compensation.

Compensation and Scheduled Payments: DHCWs who complete the study procedures including the end-of-study survey will receive $125 each. Patients who complete the LAB study procedures including the post-visit survey will be provided $100 and patients who complete the POC study procedures including the post-visit survey will be provided $50.

Additional Plans to Minimize Missing or Incomplete Data: The following will minimize missing or incomplete data:

- When appropriate, REDCap survey data fields are set to "required".
- REDCap validation rules on data fields to limit responses to those which are valid

5.4 Participant Withdrawal or Discontinuation from Study Procedures/ Intervention

5.4.1 Reasons for Participant Withdrawal or Discontinuation from Study Procedures/ Intervention

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue an individual's participation in an intervention or withdraw an individual from the study if:

- The participant has a serious adverse event requiring hospitalization.

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

5.4.2 Handling of Participant Withdrawals from Study

Participants may withdraw participation consent at any time, either verbally or in writing. Participants who further withdraw their consent for the use of data already collected must do so in writing. The Node Coordinator will interview the participant and document the withdrawal of consent using the Consent Withdrawn Received Form in the REDCap system. Documentation includes the date, the reason for participant withdrawal, as well as the upload of any written withdrawal request. Upon withdrawal, all study procedures would cease, however, the participant would be offered continued care as part of the normal standard of care.

Participants who withdraw will not be replaced.

5.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to Dr. Cecile Feldman and the funding agency (NIDCR). The principal investigator will also promptly inform the sIRB and NIDCR and will provide the reason(s) for the termination or suspension.

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

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

6 STUDY SCHEDULE

6.1 Dental Health Care Worker Subjects

The following is the schedule of events for Dental Health Care Worker Subjects in the POC Offices.

Visit	Day	Dental Health Care Worker Subjects Activities Performed
Enrollment (15 minutes)	Day -28 (+/- 29 days)	• Obtain written Informed Consent
Start-of-Study (35 minutes)	Day 0	• Complete Start-of-Study Survey • Complete Start-of-Study Triage Case Report • Undergo POC (antigen) COVID-19 test • Provide specimen for ELISA (antibody) test
Mid-Study (20 minutes)	Day 14 (+/- 7 days)	• Complete Mid-Study Triage Case Report • Undergo POC Covid-19 Test
End-of-Study (40 minutes)	Day 28 (+/- 14 days)	• Complete End-of-Study Triage Case Report • Undergo POC COVID-19 Test • Provide specimen for ELISA (antibody) test • Complete End-of-Study Survey • Complete DHCW Participation Questionnaire

The following is the schedule of events for Dental Health Care Worker Subjects in the LAB Offices.

Visit	Day	Dental Health Care Worker Subjects Activities Performed
Enrollment (15 minutes)	Day -28 (+/- 29 days)	• Obtain written Informed Consent
Start-of-Study (35 minutes)	Day 0	• Complete Start-of-Study Survey • Complete Start-of-Study Triage Case Report • Provide specimen(s) for PCR (viral) test • Provide specimen for ELISA (antibody) test
Mid-Study (20 minutes)	Day 14 (+/- 7 days)	• Complete Mid-Study Triage Case Report • Undergo POC Covid-19 Test
End-of-Study (40 minutes)	Day 28 (+/-14 days)	• Complete End-of-Study Triage Case Report • Provide specimen(s) for PCR (viral) test • Provide specimen for ELISA (antibody) test • Complete End-of-Study Survey • Complete DHCW Participation Questionnaire

6.2 Patient Subjects

The following is the schedule of events for patients participating in the POC Offices.

Visit	Day	POC Subjects Activities Performed in POC Offices
4 Weeks Prior (5 minutes)	Day -28 (+/- 14 days)	• Letter sent to providing study background to patient
2 Weeks Prior (15 minutes)	Day -14 (+/- 14 days)	• Potential subjects contacted to introduce and determine interest in the study • Obtain electronic consent signature • Complete Patient Pre-Visit Survey
Visit (35 minutes)	Day 1	• Complete Start-of-Visit Triage Case Report • Undergo POC Test • (Provision of Dental Treatment - not part of research protocol) • Complete Patient End-of-Visit Survey • Complete Patient Participation Questionnaire

The following is the schedule of events for patients participating in the LAB Offices.

Visit	Day	POC Subjects Activities Performed in LAB Offices
4 Weeks Prior (5 minutes)	Day -28 (+/- 14 days)	• Letter sent to providing study background to patient
2 Weeks Prior (15 minutes)	Day -14 (+/- 7 days)	• Potential subjects contacted to introduce and determine interest in the study • Obtain electronic consent signature • Complete Patient Pre-Visit Survey
1 Week Prior (30 - 60 minutes)	Day -7 (+/- 5 days)	• Provide specimen for PCR (viral) test • Drop specimen off at a UPS store or UPS Dropbox
Visit (20 minutes)	Day 1	• Complete Start-of-Visit Triage Case Report • (Provision of Dental Treatment - not part of research protocol) • Complete Patient End-of-Visit Survey • Complete Patient Participation Questionnaire

6.3 Unscheduled Visit

Not applicable. For dental patient participants, the study takes place during 1 patient dental visit. For Dental Healthcare Workers, data collection occurs at three specific times over a one-month period: start, mid-month, end of month.

7 STUDY PROCEDURES/EVALUATIONS

In general, the study will include completion of COVID-19 triage case reports, completion of COVID-19 testing, and administration of perception and attitude surveys. The DHCW Start-of-Visit, Mid-Visit and End-of-Visit and the Patient Start-of-Visit triage case report will include recording of temperatures and pulse oximeter reading for participants in both POC and LAB offices. During day 1, the dental visit, normal patient care will be provided to the patient subject.

Group 1- DHCWs in POC Office

Consent Process for Group 1- DHCWs in POC Offices
Within 4 weeks prior to study initiation in the dental office, the National Dental PBRN Node Coordinator will consent the DHCWs in the participating office. The consent will clearly outline participant expectations and offer the opportunity for potential participants to contact the National Dental PBRN Node Coordinator for more information as needed. DHCWs who elect to participate will affirm their willingness to participate by signing the consent form.

Study Procedures for Group 1- DHCWs in POC Offices
Prior to study initiation (Up to 4 weeks prior)

- Complete consent for all DHCW participants

Day 1

- Complete an electronic survey: *DHCW Start of Study Survey*
    - 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
- Undergo a three-part COVID-19 triage screening*
    - Symptom questions
        - Presence or absence of:
            - 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
    - Temperature check
    - Pulse oximeter reading
- Complete two COVID-19 related tests**
    - SARS-CoV-2 POC test (administered by the PBRN practitioner or designated investigator)
        - A nasal swab will be swept inside the participant's nose (not beyond the nares) to collect the specimen for the SARS-CoV-2 test
        - The office staff will process the specimen in the dental office
    - ELISA Antibody test (specimen collected by the PBRN practitioner, designated investigator or self)
        - A small lancet will create a finger prick to collect a small blood sample for collection using a Mitra cartridge (blood specimen collection device)

- The Mitra cartridge will be packaged by the DHCW and placed in the practice collection box to await shipment to Rutgers
- The sample will be processed by the Public Health Research Institute (PHRI) Lab at Rutgers

Mid-Study- Day 14 (+/- 7 days)

- Undergo a COVID-19 triage screening in the office*
- Complete a SARS-CoV-2 POC test** (administered by the PBRN practitioner or designated investigator)
  - A nasal swab will sweep the inside of the participant's nose (not beyond the nares) to collect your specimen for the SARS-CoV-2 test
  - The office staff will process the specimen

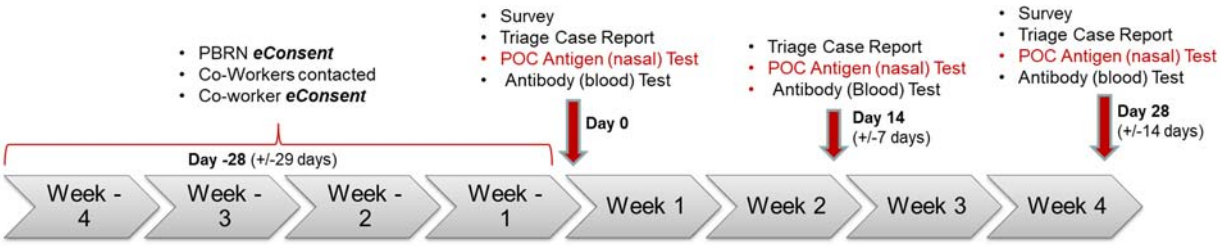
End of Study- Day 28 (+/- 7 days)

- Undergo a three-part COVID-19 triage screening*
  - Symptom questions
  - Temperature check
  - Pulse oximeter reading
- Complete two SARS-CoV-2 tests**
  - SARS-CoV-2 POC test (administered by PBRN practitioner or designated investigator)
    - A nasal swab will be swept inside the participant's nose (not beyond the nares) to collect the specimen for the SARS-CoV-2 test
    - The office staff will process the specimen in the dental office
  - ELISA Antibody test (specimen collected by the PBRN practitioner, designated investigator or self)
    - A small lancet will create a finger prick to collect a small blood sample for collection using a Mitra cartridge (blood specimen collection device)
    - The Mitra cartridge will be packaged by the DHCW and placed in the practice collection box to await shipment to Rutgers
    - The sample will be processed by the Public Health Research Institute (PHRI) Lab at Rutgers
- Complete two electronic surveys:
  - *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

*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 hay fever which likely explains sneezing or a report of physical activity which likely explains muscle soreness), the DHCW will be referred to their primary care physician for further testing.

- Positive screening includes having one or more symptoms of unknown origin
- A positive temperature is considered greater than 100.4 degrees F
- A positive pulse oximeter is considered when the blood oxygen saturation level is below 95%

**If the POC COVID-19 test is positive, the DHCW may be dismissed from duties and instructed to consult with their primary care provider for further testing.



Group 2- Patients in POC Offices

Consent Process for Group 2- *Patients in POC Offices*

Three weeks (+/- 20 days) prior to visit, patients will get an introductory/interest letter, informing them about the study and that they may be receiving a phone call to determine their interest. About two weeks prior to their scheduled dental visit, patients will be contacted by the dental office to determine their willingness to participate in the study. Patients who indicate interest will be sent an email link, which opens the consent. Patients will be able to speak to the PBRN practitioner or approved staff member with any questions or seek clarifications. The consent will clearly outline participant expectations and offer the opportunity for potential participants to contact the office for more information as needed. Participants who elect to participate will affirm their willingness to participate by clicking the "*I agree to take part in this study*" button at the end of the consent form.

Study Procedures for Group 2- Patients in POC Offices

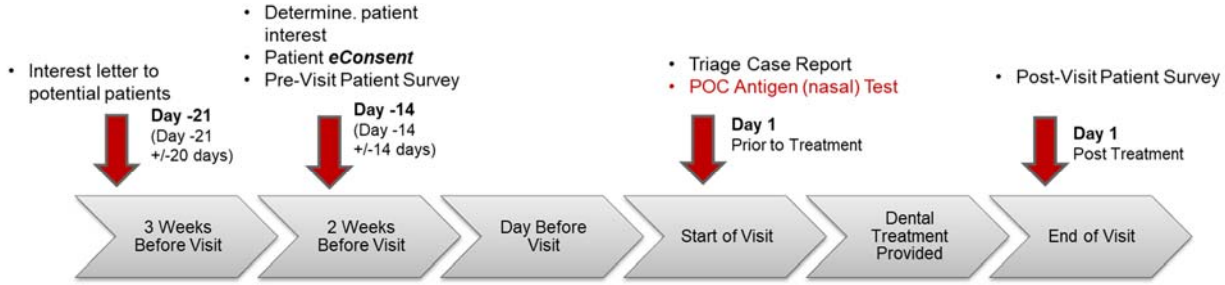
Study participants will be asked to do the following:

- Two weeks before the dental visit
  - Complete and sign electronic consent
  - Complete an electronic survey: *Patient Pre-Visit Survey*
    - Questions 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
    - Launched automatically after the completed consent
- At the start of the Dental Visit
  - Undergo a COVID-19 triage screening in the office*
    - Screening includes symptom questions, temperature check, and pulse oximeter reading
  - Complete COVID-19 POC test** (administered by PBRN practitioner or designated investigator)
    - A nasal swab will be swept inside the participant's nose (not beyond the nares) to collect the specimen for the COVID-19 test
    - The PBRN Practitioner or their designee will process the specimen
- At the End of the Dental Visit
  - Complete two electronic surveys
    - *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
    - *Patient Participation Survey*
      - Questions explore perceptions related to study participation including survey and testing logistics

*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 hay-fever which likely explains sneezing or a report of physical activity which likely explains muscle soreness), appointment will be postponed, and the participant will be referred to their primary care physician for further testing.

- A Positive screening by reporting one or more symptoms of unknown origin
- A positive temperature is considered greater than 100.4 degrees F
- A positive pulse oximeter is considered when the blood oxygen saturation level is below 95%

**If the POC COVID-19 test is positive, the dental visit may be postponed, and the positive patient participant will be instructed to consult with their primary care provider for further testing.



Group 3- DHCWs in LAB Offices

Consent Process for Group 3- DHCWs in LAB Offices

Within 4 weeks prior to study initiation in the dental office, the National Dental PBRN Node Coordinator will consent the DHCWs in the participating office. The consent will clearly outline participant expectations and offer the opportunity for potential participants to contact the National Dental PBRN Node Coordinator for more information as needed. DHCWs who elect to participate will affirm their willingness to participate by signing the consent form.

Study Procedures for Group 3- DHCW in LAB Offices

Prior to study initiation (Up to 4 weeks prior)

- Complete consent for all DHCW participants

Day 1

- Complete an electronic survey: *DHCW Start of Study Survey*
    - 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
- Undergo a three-part COVID-19 triage screening*
    - Symptom questions
        - Presence or absence of:
            - 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
    - Temperature check
    - Pulse oximeter reading
- Complete two COVID-19 related tests**
    - SARS-CoV-2 PCR viral test
    - Saliva (self-collected) and tongue specimens (collected by PBRN practitioner, designated investigator or self)
    - ELISA Antibody test (specimen collected by PBRN practitioner, designated investigator or self)
        - A small lancet will create a finger prick to collect a small blood sample for collection using a Mitra cartridge (blood specimen collection device)
        - The Mitra cartridge will be packaged by the DHCW and placed in the practice collection box to await shipment to Rutgers
        - The sample will be processed by the Public Health Research Institute (PHRI) Lab at Rutgers

Mid-Study- Day 14 (+/- 7 days)

- Undergo a COVID-19 triage screening in the office*
- Complete a SARS-CoV-2 PCR Viral test**
    - Saliva (self-collected)

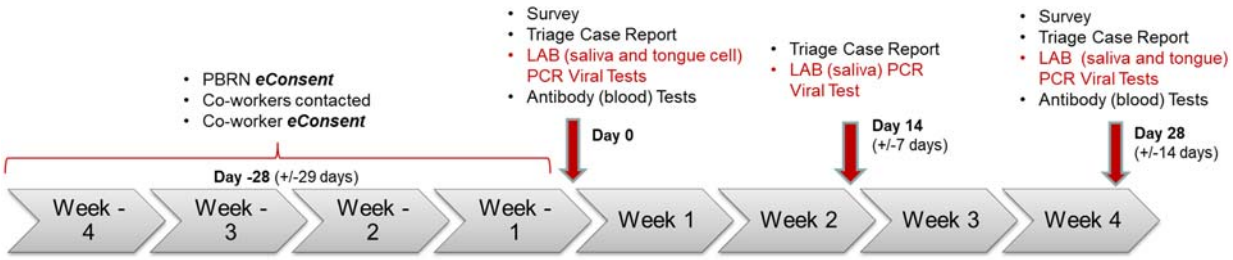
End of Study- Day 28 (+/- 7 days)

- Undergo a three-part COVID-19 triage screening*
    - Symptom questions
    - Temperature check
    - Pulse oximeter reading
- Complete two SARS-CoV-2 tests**
    - SARS-CoV-2 PCR viral test
    - Saliva (self-collected) and tongue specimens (collected by PBRN practitioner, designated investigator or self)
    - ELISA Antibody test (specimen collected by PBRN practitioner, designated investigator or self)
        - A small lancet will create a finger prick to collect a small blood sample for collection using a Mitra cartridge (blood specimen collection device)
        - The Mitra cartridge will be packaged by the DHCW and placed in the practice collection box to await shipment to Rutgers
        - The sample will be processed by the Public Health Research Institute (PHRI) Lab at Rutgers
- Complete two electronic surveys:
    - *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

*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 hay-fever which likely explains sneezing or a report of physical activity which likely explains muscle soreness), the DHCW will be referred to their primary care physician for further testing.

- Positive screening includes having one or more symptoms of unknown origin
- A positive temperature is considered greater than 100.4 degrees F
- A positive pulse oximeter is considered when the blood oxygen saturation level is below 95%

**If the lab processed SARS-CoV-2 test is positive, the DHCW may be dismissed from duties and instructed to consult with their primary care provider for further testing.



Group 4- Patients in LAB Offices

Consent Process for Group 4 - *Patients in LAB Offices*

Three weeks (+/- 14 days) prior to a scheduled dental visit, patients will get an introductory/interest letter, informing patients about the study and that they may be receiving a phone call to determine their interest. About two weeks prior to their scheduled dental visit, patients will be contacted by the dental office to determine their willingness to participate in the study. Patients who indicate interest will be sent an email link, which opens the consent. Patients will be able to speak to the PBRN practitioner or approved staff member with any questions or seek clarifications. The consent will clearly outline participant expectations and offer the opportunity for potential participants to contact the office for more information as needed. Participants who elect to participate will affirm their willingness to participate by clicking the "*I agree to take part in this study*" button at the end of the consent form.

Study Procedures for Group 4 - Patients in LAB Offices

Study participants will be asked to do the following:

- Two weeks before the dental visit
  - Complete and sign electronic consent
  - Complete an electronic survey: *Patient Pre-Visit Survey*
    - Questions 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
    - Launched automatically after the completed consent
  - Receive a saliva collection kit by mail
- One week before the dental visit
  - Complete a COVID-19 saliva test
    - Spit into a tube
    - Package as directed
  - Drop off the completed test kit at a UPS Store or drop-off box
- At the start of the Dental Visit
  - Undergo a COVID-19 triage screening in the office*
    - Screening includes symptom questions, temperature check, and pulse oximeter reading
- At the End of the Dental Visit
  - Complete two electronic surveys
    - *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

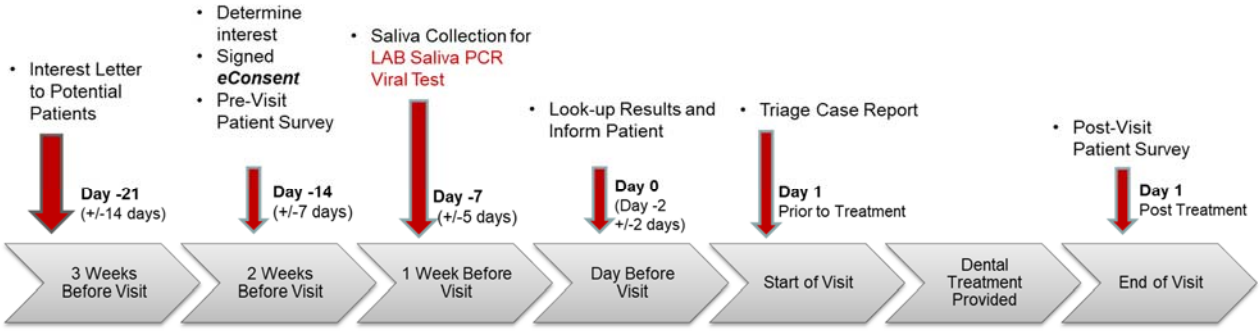
▪ *Patient Participation Survey*

- Questions explore perceptions related to study participation including survey and testing logistics

*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 hay-fever which likely explains sneezing or a report of physical activity which likely explains muscle soreness), the appointment will be postponed, and the participant will be referred to their primary care physician for further testing.

- A Positive screening by reporting one or more symptoms of unknown origin
- A positive temperature is considered greater than 100.4 degrees F
- A positive pulse oximeter is considered when the blood oxygen saturation level is below 95%

**If the lab processed SARS-CoV-2 test is positive, the dental visit may be postponed, and the positive patient participant will be instructed to consult with their primary care provider for further testing.



Reporting and Notification

The results of the POC, LAB, and/ Elisa test will be recorded in the *Testing Case Report* form in REDCap. The PI and/or Chief Protocol Officer will notify the Practitioner of test results. The National Dental PBRN dentist member of the practice will be considered the "Practitioner" of the office and assume the responsibility of notifying test results to the DHCWs and patients in the practice.

For the purpose of this study, a COVID-19 positive result is not considered an adverse event though results of this test will be recorded.

DHCW subjects who test antigen or viral positive or who triage positive without any preexisting medical condition will be instructed to speak to their physicians for a definitive diagnosis and follow-up. If a DHCW is back to work in time for the mid-study testing, the mid-study protocol will be followed. Similarly, if a DHCW can return to work in time for the end-of-study testing, the end-of-study protocol will be followed. In either case, a follow-up call by the PBRN practitioner or designated investigator will be made approximately 1 week after the positive triage finding or test result to record any confirmatory tests which were obtained based upon the advice of the DHCW's physician.

Patient subjects who are COVID-19 antigen or viral positive or who triage positive without any preexisting medical condition, will not be seen for their scheduled dental visit. The subject will be referred to their physician for a definitive diagnosis and follow-up.

7.1 Study Procedures/Evaluations

The following study procedures will be completed

Group 1- DHCW Subjects in POC Offices

Procedure and Evaluations	Purpose	Completed as Part of Study	When Completed	Who Completes
Complete Consent	Complete informed consent	Yes	**Prior to Enrollment**	Study investigators meet with subjects and document consent in REDCap
Start-of-study DHCW Survey • PPE used • Environmental Controls Used • Perception of Importance • Comfort • Safety • COVID-19 Testing Preferences • Vaccination Opinions	Collect baseline Outcomes measures	Yes	**Start-of-Study** (day 0)	Data entered via REDCap self-administered survey
Triage Case Reports	Collect COVID-19 screening data	Yes	**Start-of-Study** (Day 0) **Mid-Study** (Day 14) **End of Study** (Day 28)	Data entered into REDCap via eCRF by the Practitioner
Testing Case Reports	Collect information on outcomes of COVID-19 testing	Yes	**Start-of-Study** (Day 0) **Mid-Study** (Day 14) **End of Study** (Day 28)	***POC Test*** POC SARS-CoV-2 antigen test results entered into REDCap by the Practitioner or designated investigator for all DHCWs ***ELISA Ab test*** **For Practitioner-** Data entered into REDCap eCRF by the PI and/or Chief Clinical Officer **For other DHCWs-** Data entered into REDCap eCRF by the PI and/or Chief Clinical Officer
End-of-Study DHCW Survey	Collect payment information	Yes	**End-of-Study** (Day 28)	Data entered via REDCap self-administered survey.
Dental Health Care Participation Questionnaire	Collect feasibility information on surveys and logistics	Yes	**End-of-Study** (Day 28)	Data entered via REDCap self-administered survey.

Group 2- Patient Subjects in POC Offices

Procedure and Evaluations	Purpose	Completed as Part of Study	When Performed	How Completed
Obtain Informed Consent	Complete informed consent	Yes	**2 Weeks Prior** (day -14 +/-14 days)	Electronic consent and signatures obtained prior to initiating Pre-Visit Patient Survey
Patient Start-of-Visit Survey • Safety and Comfort • COVID-19 Testing Preferences • Perception of Importance • Medical history Likelihood to report COVID-19 symptoms	Collect outcome measures	Yes	**2 Weeks Prior** (day -14 +/- 14 days)	Data entered via REDCap self-administered survey.
Triage Case Report	Collect COVID-19 screening data	Yes	**Visit** (day 1)	Data entered into REDCap via eCRF by the Practitioner or their investigator designee
Testing Case Reports	Collect information on outcomes of COVID-19 testing		**Visit** (day 1)	POC SARS-CoV-2 antigen test results entered into REDCap via eCRF by the Practitioner or their investigator designee
Dental Procedures Performed	Maintain patient oral health	**NO**	**Visit**	Completed by Dental Health Care Workers
End-of-Visit Patient Survey • PPE observed in office • Environmental controls observed in office	Collect outcome measures	Yes	**Visit** (day 1)	Data entered via REDCap self-administered survey.
Patient Participation Questionnaire	Collect feasibility information on surveys and logistics	Yes	**End of Study** (Day 28)	Data entered via REDCap self-administered survey.

Group 3- DHCW Subjects in LAB Offices

Procedure and Evaluations	Purpose	Completed as Part of Study	When Completed	Who Completes
Complete Consent	Complete informed consent	Yes	**Prior to Enrollment**	Study investigators meet with subjects and document consent in REDCap
Start-of-study DHCW Survey • **PPE used** • **Environmental Controls Used** • **Perception of Importance** • **Comfort** • **Safety** • **COVID-19 Testing Preferences** • **Vaccination Opinions**	Collect baseline Outcomes measures	Yes	**Start-of-Study** (day 0)	Data entered via REDCap self-administered survey
Triage Case Reports	Collect COVID-19 screening data	Yes	**Start-of-Study** (Day 0) **Mid-Study** (Day 14) **End of Study** (Day 28)	Data entered into REDCap via eCRF by the Practitioner or designated investigator
Testing Case Reports	Collect information on outcomes of COVID-19 testing	Yes	**Start-of-Study** (Day 0) **Mid-Study** (Day 14) **End of Study** (Day 28)	***PCR Viral and ELISA Ab tests*** **For the Practitioner-** Data entered into REDCap eCRF by the PI and/or Chief Clinical Officer **For the other DHCWs-***Data entered into REDCap eCRF by* the PI and/or Chief Clinical Officer
End-of-Study DHCW Survey	Collect payment information	Yes	**End-of-Study** (Day 28)	Data entered via REDCap self-administered survey.
Dental Health Care Participation Questionnaire	Collect feasibility information on surveys and logistics	Yes	**End-of-Study** (Day 28)	Data entered via REDCap self-administered survey.

Group 4- Patient Subjects in LAB Offices

Procedure and Evaluations	Purpose	Completed as Part of Study	When Performed	How Completed
Obtain Informed Consent	Complete informed consent	Yes	**2 Weeks Prior** (day-14 +/-7 days)	Electronic consent and signatures obtained prior to initiating Pre-Visit Patient Survey
Patient Start-of-Visit Survey • Safety and Comfort • COVID-19 Testing Preferences • Perception of Importance • Medical history Likelihood to report COVID-19 symptoms	Collect outcome measures	Yes	**2 Weeks Prior** (day-14 +/-7 days)	Data entered via REDCap self-administered survey.
Triage Case Report	Collect COVID-19 screening data	Yes	**Visit** (day 1)	Data entered into REDCap by the PI and/or Chief Clinical Officer
Testing Case Reports	Collect information on outcomes of COVID-19 testing		**Day Prior** (day -2 +/-2 days	Saliva Viral SARS-CoV-2 test results entered into REDCap via eCRF by the Practitioner or their investigator designee
Dental Procedures Performed	Maintain patient oral health	**NO**	**Visit**	Completed by Dental Health Care Workers
Patient End-of-Visit Survey • PPE observed in office • Environmental controls observed in office	Collect outcome measures	Yes	**Visit** (day 1)	Data entered via REDCap self-administered survey.
Patient Participation Questionnaire	Collect feasibility information on surveys and logistics	Yes	**End of Study** (Day 28)	Data entered via REDCap self-administered survey.

7.2 Laboratory Procedures/Evaluations

7.2.1 Clinical Laboratory Evaluations

DHCW (dentists, hygienist, assistants and front desk personnel) and patient subjects will be tested for COVID-19. DHCW will be administered POC, PCR Viral Test and/or ELISA Antibody Test. LAB patient subjects will be administered the LAB test and POC patient subjects will be administered the POC test.

	POC Test (Antigen)	DHCW PCR Viral Test	DHCW ELISA Antibody Test
Test Description			
Company	BD Veritor System or Abbott COVID-19 antigen card test Kits	Rutgers	Rutgers
Sample collected via	Nasal swab	Saliva collection tube with buffer and/or tongue cells via cytology brush	Capillary blood sample via Neoteryx Mitra Cartridge
What is being Tested	SARS-CoV-2 Nucleocapsid Antigen	SARS-CoV-2 RNA	IgG and IgM
Test Administration (specimen collection)	Nasal swab performed by PBRN Practitioner or designated investigator (not beyond the nares)	Performed by PBRN Practitioner, designated investigator or self	Performed by PBRN Practitioner, designated investigator or self
Test Administration (specimen processing)	BD Veritor or Abbott COVID-19 antigen card test performed by PBRN Practitioner or designated investigator	Department of Oral Biology, Rutgers School of Dental Medicine and/or Genomics Laboratory, New Jersey Medicine School	Mitra Cartridge is processed at ICPH-PHRI center, New Jersey Medical School, Newark, NJ
Results	Dichotomous (+ or -)	Quantitative	Quantitative

With regard to the quality of the SARS-CoV-2 test specimen, the following will be used to assess the quality of the specimen.

	POC Test	PCR Viral Test	ELISA Antibody Test
Indication of Proper Processing	The Veritor instrument will report if a sample is not able to be processed or control line on the Abbot COVID-19 antigen card will not be able to be seen. This feedback will be used to identify insufficient training or unanticipated problems.	The Oral Biology Lab and/or Genomics Laboratory will report if a sample is not able to be processed. This feedback will be used to identify insufficient training or unanticipated problems.	ICPH will report if a sample is not able to be processed. This feedback will be used to identify insufficient training or unanticipated problems.

7.2.2 Specimen Preparation, Handling, and Storage

The following details specimen preparation, handling and storage.

	POC Test	PCR Viral Test	ELISA Antibody Test
Sample Collection & Shipping			
Sample Collection Materials	Nasal swab included in BD Veritor or Abbott COVID-19 antigen card system	Saliva collection kit via Spectrum and/or Tongue cell collection kit via Oral Biology Laboratory	Capillary blood sample via Mitra Cartridge
Storage of Specimen Collection Supplies and Test Kits	National Dental PBRN Office after kits are mail to them from the Clinical Research Center at the Rutgers School of Dental Medicine	National Dental PBRN Office after kits are mail to them from the Clinical Research Center at the Rutgers School of Dental Medicine	National Dental PBRN Office after kits are mail to them from the Clinical Research Center at the Rutgers School of Dental Medicine

Transport Media	Not applicable (POC Test)	Buffer solution	Sponge with capillary blood is transported with desiccant
Packaging Specimen for Shipping	Not applicable (POC Test)	Sealed biohazard plastic bag placed into a 95 kPa bio-hazard bag with absorbent which is placed into a UN3373 Category B certified box.	Post sampling, the closed Mitra Cartridge is inserted into sealed specimen bag which contains a decedent that absorbs moisture, and inserted in a shipping UN3373 Category B certified box.
Sample Processing (Performing the Test)			
Processing Supplies	Included in point-of-care BD Veritor or Abbott COVID-19 antigen card	RNA extraction, followed by RT-PCR	96 well plate, ELISA reagents
Processing Time	15 minutes	About four hours	Overnight extraction at 4C, followed by automated ELISA
Conditions for Stability and Transport Condition			
Stability prior to Use	No special storage conditions required	No special storage conditions required	No special storage conditions required Dry blood on Mitra Cartridge stable at room temperature for 28 days.
Stability during shipping	Not applicable (POC Test)	Yes due to transport media	Yes due to desiccant
Storage prior to processing	Not applicable (POC Test)	Oral Biology Laboratory and/or Genomics Laboratory	PHRI Laboratory
Stability prior to processing	Stable at room temperature	Stable at room temperature	Stable at room temperature
Tracking			
Labeling	Not applicable (POC Test)	Specimen ID (bar code) Subject ID (bar code) Subject Name Date of Specimen	Specimen ID (bar code) Subject ID (bar code) Subject Name Date of Specimen
Tracking of Specimen Collection Kits	Not applicable (POC Test)	REDCap System and/or Excel Worksheet	REDCap System and/or Excel Worksheet
Tracking of Tests Administered	Completion of REDCap SARS-CoV-2 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)	Completion of REDCap SARS-CoV-2 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)	Completion of REDCap SARS-CoV-2 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)
Results			
Processing Time	15 minutes	Results are available within 1 week.	Results are available within 1 week
Recording Results in REDCap	Via posting in REDCap by PBRN Practitioner or designated investigator	Via secure e-mail and web site and then posted into REDCap by the Rutgers research staff	Via secure e-mail and then posted into REDCap by the Rutgers research staff
Notifying participants	National Dental PBRN Practitioner or designated investigator	**PBRN Practitioner results**- by the PI and/or Clinical Chief **DHCW and Patient results**- by the National Dental PBRN Practitioner or designee	**PBRN Practitioner results**- by the PI and/or Clinical Chief **DHCW and Patient results**- by the National Dental PBRN Practitioner or designated investigator
Reporting to State Department of Health	PI, Chief Clinical Officer, PBRN Practitioner or designated investigator	Genomics Laboratory	Not Applicable

7.2.3 Specimen Shipment

Saliva for LAB, and nasal swab for the PCR Viral Test specimens are collected and immediately placed into a preservative. The Mitra Cartridge includes a desiccant or sample preservation. All can be stored at room temperature for at least one week.

	POC Test	PCR Viral Test	ELISA Antibody Test
Shipment Method and Frequency	Not applicable	Samples will be obtained from subjects Monday and Wednesday and sent to the Rutgers School of Dental Medicine via UPS or Federal Express.	Specimens will be mailed via UPS or Federal Express.
Packaging Specimen for Shipping	Not applicable (POC Test)	Specimens are placed into biohazard plastic bag, sealed then placed into a 95 kPa bio-hazard bag with absorbent, sealed and then placed into a UN3373 Category B certified box.	Post sampling, the closed Mitra Cartridge is inserted into sealed specimen bag which contains a decedent that absorbs moisture then placed into a 95 kPa bio-hazard bag with absorbent and inserted in a shipping UN3373 Category B certified box.
Shipping Address	Not applicable	Rutgers University School of Dental Medicine 110 Bergen Street Newark, NJ 07103	Rutgers University School of Dental Medicine 110 Bergen Street Newark, NJ 07103
Contact Information for Laboratory Personnel	Not applicable	Dr. Daniel Fine Phone: (973) 972-7056 finedh@sdm.rutgers.edu Dr. Patricia Soteropoulos Phone: (973) 972- 3890 soteropa@njms.rutgers.edu	Dr. Maria Gennaro Phone: (973) 854-=3210 Marila.gennaro@rutgers.edu
Days and Times shipments are allowed	Not applicable	Monday thru Friday 9:00 am to 5:00 pm	Monday thru Thursday 9:00 am to 5:00 pm
Labeling Requirements for Specimen Shipping	Not applicable	Subject Number, Subject Name, and Collection Tube ID/Bar Code	Subject Number, Subject Name and Mitra Cartridge ID/Bar Code
Special Instruction for Specimen Collection	No special instructions	Subject should not eat or drink for 30 minutes prior to saliva and tongue cell specimen collection	Clean area for finger prick with alcohol gauze prior to pricking finger
Special Instructions for Specimens for Shipment (i.e., dry ice, wet ice)	Not applicable	No special instructions	No special instructions
Completion of Specimen-Tracking Log	Completion of REDCap COVID-19 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)	Completion of REDCap COVID-19 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)	Completion of REDCap COVID-19 Test Order and Results Form (which enables the generation of a Specimen Tracking Log)

8 ASSESSMENT OF SAFETY

8.1 Definitions and Specifications of Safety Parameters

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

Event	Definition	Form	Who completes REDCap form	Time Frame For Reporting to sIRB	Additional Reports
Unanticipated Problems	Any problem or event which was: 1. Unexpected (in nature, severity, or frequency) AND 2. Is related or possibly related to participation in the research AND 3. Reflects new increased risk to the subjects	Unanticipated Problem Form	National Dental PBRN Node Coordinator or Node Director	If the UP is also an SAE, submit the UP form within 5 working days to the CIRB directly If the UP is not an SAE, submit to CIRB and to NIDCR within 2 weeks of becoming aware of the problem.	NIDCR via Rho Product Safety (Simultaneously with IRB)
Adverse Event	When an investigator receives a report of an external adverse event, the investigator should review the report and assess whether it identifies the adverse event as being: 1. unexpected; 2. related or possibly related to participation in the research; and 3. serious or otherwise one that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. If the responses to the above are “yes” then it should be reported as an unanticipated problem (or an SAE, if the answer to 3. Is “yes.”)	Adverse Events Form	National Dental PBRN Node Coordinator or Node Director	Only required to submit to CIRB if UP or SAE.	Not required unless UP or SAE.
Serious Adverse Event	Serious adverse event (includes serious adverse drug or biological experience and unanticipated adverse device experiences under FDA regulations) is any adverse event temporally associated with the subject's participation in research that meets any of the following criteria: • Results in death • Is life-threatening (places the subject at immediate risk of death from the event as it occurred) • Requires inpatient hospitalization or prolongation of existing hospitalization • Results in a persistent or significant disability/incapacity • Results in a congenital anomaly/birth defect • Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention	Unanticipated Problem Form AND Serious Adverse Events Form	National Dental PBRN Node Coordinator	Submit SAE form within 24 hours if incident caused death or life threatening injury or within 72 hours for all other results to the NIDCR safety committee (*rho_productsafety@rhoworld.com*).	NIDCR via Rho Product Safety (Simultaneously with IRB), Regional IRB

	to prevent one of the other outcomes listed in this definition.				
Protocol Deviation/ Violation	Deviations: Any change, divergence, or departure from the study procedures described in the IRB-approved clinical protocol Violation: Any deviation from the sIRB approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data	Protocol Deviation/ Violation Form	National Dental PBRN Node Coordinator or Node Director	10 business days from the date of discovery	Other study Sites Monthly to NIDCR on the first of the month via NIDCR Reports @rhoworld.com

Study procedures are limited to surveys and collection of biospecimens: saliva samples, capillary blood samples via finger prick, superficial tongue scraping, and nasal swab (not beyond the nares) samples. We therefore expect few, if any study related serious adverse events (SAEs). In the rare event that a SAE were to occur, an Unanticipated Problem form would be completed, and SAE reporting timelines would be followed.

8.1.1 Unanticipated Problems

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

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

8.1.2 Serious Adverse Events

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

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

If a SAE becomes known, the National Dental PBRN Practitioner or designated investigator will immediately notify the National Dental PBRN Node Coordinator who will then notify study PI. The National Dental PBRN Node Coordinator will record the event in the REDCap Unanticipated Problem form and Serious Adverse Event Form based upon information obtained.

8.1.3 Protocol Deviations/Violations

As the purpose of this pilot is to determine if the study windows are appropriate, activities taking place outside of a specified window will not be considered a protocol deviation or violation. In addition, any missed or incomplete surveys or forms will not be considered protocol deviation or violation as these are outcome measures for the pilot study.

8.2 Reporting Procedures

8.2.1 Unanticipated Problem Reporting

Incidents or events that meet the Office of Human Research Protection (OHRP) criteria for UPs require the creation and completion of a UP report form.

OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the sIRB:

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

To satisfy the requirement for prompt reporting, UPs will be reported that are not SAEs will be reported using the following timeline:

- Unanticipated problems that are SAEs will be reported to the sIRB as soon as possible, and no later than within 5 business days of the investigator becoming aware of the event.
- Any other UP will be reported to the sIRB as soon as possible but within 10 business days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the sIRB's receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR concurrently with reporting to the sIRB. These reports will be made to NIDCR's centralized reporting system via the Clinical Research Operations and Management Support (CROMS) contractor.

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

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

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

9 STUDY OVERSIGHT

The PI will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PI will review the data for safety concerns and data trends at regular intervals and will promptly submit reportable events to the sIRB and NIDCR that arise during the conduct of the study.

10 CLINICAL SITE MONITORING

No outside clinical site monitoring will be employed for this study. The PI and staff will closely monitor adherence to the study protocol and study processes throughout the study. They will ensure that quality management activities occur and will evaluate study processes and documentation based on the International Council for Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP), and internal quality management plans. The NIDCR reserves the right to conduct independent clinical site monitoring as necessary.

11 STATISTICAL CONSIDERATIONS

This is a feasibility study to assess feasibility to conduct study procedures and refine trial study logistics. No sample size calculations are being performed.

11.1 Final Analysis Plan

Data to be collected includes:

Item	Type of Variable
Willingness to Participate • Dentist, Hygienist, Assistant and Front Desk personnel willing to participate • Patient willingness to participate	• Willingness to participate (Binary – Yes/No)
Triage Survey	• Ease of Administration (3 point Likert Scale) ○ Very easy to complete survey due to administration method ○ Easy to administer complete survey due to administration method ○ Not easy to complete survey due to survey administration method • Completeness (Binary – Yes/No) • Question understandability (3 point Likert Scale) ○ Very clear to understand ○ Understandable with some clarification provided by the administrator ○ Not clear to understand
Safety Perception Survey • Start-of-Study DHCW Survey • End-of-Study DHCW Survey • Start-of-Visit Patient Survey • End-of-Visit Patient Survey	• Administration method (3 point Likert Scale) ○ Very easy to complete survey due to administration method ○ Easy to complete survey due to administration method ○ Not easy to complete survey due to administration method • Completeness (Binary – Yes/No) • Question understandability (3 point Likert Scale) ○ Very clear to understand ○ Understandable with some clarification provided by the administrator ○ Not clear to understand
Testing Logistics • LAB – saliva SARS-CoV-2 viral test • POC – BD Veritor COVID-19 antigen test • PCR viral SARS-CoV-2 test • ELISA antibody SARS-CoV-2 test	• Specimen Collection (3 point Likert Scale) ○ Very easy to collect ○ Easy to collect ○ Not easy to collect • Specimen preparation for shipping (3 point Likert Scale) ○ Very easy to prepare ○ Easy to prepare ○ Not easy to prepare • Specimen storage (Binary – Easy/Not Easy) ○ Easy to Store ○ Not easy to store • Timeliness of results (3 point Likert Scale) ○ Very timeless access to results ○ Timely access to results ○ Access to results not timely • Reporting of results (3 point Likert Scale) ○ Very easy to access results ○ Easy to access results ○ Not easy to access results
Testing Case Report	• Completeness (Binary – Yes/No)

Descriptive statistics (frequencies) for all variables will be performed.

12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

All study survey information will be captured electronically and stored on secure, encrypted Rutgers University servers.

- Patient consents will be captured and recorded directly into the REDCap system.
- All Patient and DHCW surveys will be recorded directly into REDCap via the following REDCap forms:

DHCW Participants	Patient Participants
Start-of-Study DHCW Survey	Triage Case Report
Triage Survey Case Report	Pre-Visit Patient Survey
End-of-Study DHCW Survey	End-of-Visit Patient Survey
DHCW Feasibility Study Participation Questionnaire	Patient Feasibility Study Participation Questionnaire
Testing Case Report	Testing Case Report

- Testing results will be captured in the REDCap Testing Case Report in the following ways:

	POC	PCR	ELISA
Original Source Document	N/A – Results appear on BD Veritor Screen or Abbott COVID-19 antigen test card and directly recorded into REDCap	Excel Spreadsheet posted onto SDM PREDICT box drive	Excel Spreadsheet posted onto SDM PREDICT box drive
Storage of Original Source Document	Not Applicable	Electronically stored on Rutgers server	Electronically stored on Rutgers server
Responsibility for Entering into REDCap	National Dental PBRN Practitioner or their investigator designee	Rutgers PI, Clinical Protocol Chief or their designee	Rutgers PI, Clinical Protocol Chief or their designee
Verification of Correct Entry into REDCap	Not Applicable	PI or Chief of Clinical Protocol or their designee	PI or Chief of Clinical Protocol or their designee

- At the end of the study, deidentified data will be provided to the National Coordinating Center.

All paper-based study source documents will be maintained in the Rutgers School of Dental Medicine Clinical Research Center which is located on the D Level of the Dental School Building. All documents will be secured in a locked file cabinet in the center. Access to the Clinical Research Center is limited to research center personnel via a card reader.

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of participants. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress, and data validity.

13 QUALITY CONTROL AND QUALITY ASSURANCE

Quality Management (QM) measures will occur throughout this study to ensure adherence to protocol and collection of complete and accurate data. QM activities include those measures done as part of daily standard operating procedures by staff at each site and by the data management controls built into the PREDICT REDCap. QM activities will include activities undertaken at defined intervals to ensure that all study personnel have undergone training prior to initiating the protocol, QM activities are occurring, and study-related documents are up-to-date.

Staff Training

Training of all staff will be conducted and recorded in training logs. Each staff member has been identified by role. Records of completed training will be maintained by the node coordinator on the NCC Hub.

Training Modules	Who Will be Trained
Human Subjects, HIPAA	• All Study Personnel
General Clinical Research Training (Human Subjects, HIPAA)	• PI, Chief of Clinical Protocol, PBRN practitioners and designated investigators
General Overall (Study Purpose, Goals and Protocol)	• All Study Personnel
REDCap System Training	• National Dental PBRN Practitioners and Designated Investigators

Daily Operating Procedures

The PI and the Chief of Clinical Protocol will follow the REDCap dashboard to ensure compliance with study procedures. The dashboard exhibits red indicators for instruments which have been started and not completed, yellow indicators for instruments which have been completed and not verified and green indicators for instruments which have been completed and reviewed. The PI or Chief of Clinical Protocol will be responsible for reviewing each instrument and changing the status from unverified to verified. Any issues with compliance with the study protocol identified by the PI or Chief of Clinical Protocol will be reviewed with the National Dental PBRN Practitioner and be used to identify any unanticipated problems and develop/implement any necessary corrective action plans.

Subject Completion Review

As this is a feasibility study, reviews of surveys and case reports to ensure completeness will not be completed, rather the number/percentage of incomplete surveys and forms will be analyzed as an outcome measure. Consent forms will be reviewed for completeness at the mid-study visit for DHCW subjects and as part of the end-of-visit survey for patient subjects.

Data Management Controls

REDCap is a rich system which enables privileging, required data element entry and required data validation to be embedded into daily operations.

- **Privileging:** Every study staff member will be assigned a role which carries specific read/write/edit/delete privileges. Staff member will be assigned a role providing minimal rights sufficient to perform his/her responsibilities.
- **Structured Data:** Whenever possible, data will be collected via structured data responses rather than free-text. Structured data requires a respondent to check a valid response.
- **Data Validation:** Data fields will be established limiting responses to those that are reasonable. For example, year of birth would have a range of 2002 (corresponding to age 18 – the youngest

eligible) to 1920 (corresponding to age 100 – more than sufficient to cover the age range of individuals having impacted 3rd molars extracted.)

- **Required Fields:** Whenever appropriate, fields have been made required so as to ensure completed forms and questionnaires.

Structured responses are required for the CRFs so only valid responses can be recorded. In addition, REDCap has been programmed with all responses being required at time of completion which will trigger an error message, but subjects can save their responses without all responses being completed. Validation rules are employed where possible.

14 ETHICS/PROTECTION OF HUMAN SUBJECTS

14.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

14.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the sIRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the sIRB before the changes are implemented in the study.

14.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be sIRB-approved, and the participant is required to read and review the document or have the document read to him or her. The investigator or their investigator designee will explain the research study to the participant and answer any questions that may arise.

All DHCWs and patient participants will review and electronically sign the informed consent document prior to any study-related assessments or procedures. For LAB and POC patient subjects, an electronic consent and signature will be obtained before the Pre-Visit-Triage survey is completed.

Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

The consent process will be documented in the clinical or research record.

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

Women and minorities will be eligible to participate. Children less than 18 years will not be able participate.

14.5 Subject Confidentiality

Subject confidentiality is strictly held in trust by the investigators, study staff, and the study sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to participants.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the study sponsor.

The study monitors or other authorized representatives of NIDCR may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (https://humansubjects.nih.gov/coc/index - Certificates of Confidentiality (CoC) – Human Subjects). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

NIH Data Sharing Policies

As described in section 17, it is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/shring.htm - NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources). PIs and funding recipient institutions will ensure that all mechanisms used to share data include proper plans and safeguards to protect the rights and privacy of individuals who participate in NIH-sponsored research.

14.6 Future Use of Stored Specimens and Other Identifiable Data

No residual specimens will be maintained after this project is completed. All Identifiable data will be destroyed 6 years after the study is completed.

15 DATA HANDLING AND RECORD KEEPING

The study PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

15.1 Data Management Responsibilities

The PIs in collaboration with the NCC will review reports of data completeness and accuracy as well as protocol compliance on an ongoing basis throughout the study.

15.2 Data Capture Methods

Other than the Testing Case Report, all data for the study be electronically captured. Various devices will be used including:

- Laptop and desktop computers to complete surveys and forms directly into REDCap, the electronic data capture system for the study
- iPads to complete surveys, forms and capture electronic signatures directly into REDCap
- Bar code scanner to label study specimens

Patients will use their own computer of personal electronic device to sign the consent form and answer the pre-visit survey. DHCW will use their own computer, electronic device, an office computer electronic device or the study provided electronic pads for consents. All other forms and surveys to be completed DHCW or patient subjects by using study provided electronic pads.

REDCap will be used to collect and maintain all study data.

	DHCW Method of Collection	DHCW Entered By Whom	PATIENTS Method of Collection	PATIENTS Entered by Whom
Surveys	Survey administered via REDCap with responses entered directly into REDCap	By study participant on office iPad	Survey administered via REDCap with responses entered directly into REDCap	By study participant on computer or other electronic device at home
Triage Survey Case Report	Survey administered via REDCap form with responses entered directly into REDCap	By PBRN Practitioner or Investigator designee	REDCap form	By PBRN Practitioner or Investigator designee
POC Test Results Case Report	Data from Veritor Reader or Abbott COVID-19 Ag Card	By PBRN Practitioner or Investigator designee	Data from Veritor Reader or Abbott COVID-19 Ag Card	By PBRN Practitioner or Investigator designee
PCR Test Results Case Report	Data entered directly of e-mail of results into REDCap Form upon receipt of secure e-mail from lab	Rutgers PI, Chief of Protocol or Designee	Data entered directly into REDCap Form upon receipt of secure e-mail from lab	Rutgers PI, Chief of Protocol or Designee
ELISA Antibody Test Results Case Report	Data entered directly from e-mail of results into REDCap Form upon receipt of secure e-mail from lab	Rutgers PI, Chief of Protocol or Designee	Data entered directly into REDCap Form upon receipt of secure e-mail from lab	Rutgers PI, Chief of Protocol or Designee

All study data will be centrally stored on the Rutgers REDCap data management system, and study-related documentation will be maintained on RSDM PREDICT Box drive. REDCap is a secure web application which is password protected and compliant with 21 CFR Part 11. Study data and documentation will be available to the study PI and core personnel in real time, per allowable permissions.

15.3 Types of Data

Types of data to be collected include DHCW and patient perceptions and attitudes, medical history, COVID-19 like symptoms (of unknown origin), temperature, pulse oximeter readings and biospecimens that will generate COVID-19 test results.

15.4 Schedule and Content of Reports

The following reports/dashboards will be developed:

Report/ Dashboard	Frequency	Purpose	Content	Reviewed by
Unanticipated Problem (including Serious Adverse events and protocol deviations) Report	Quarterly	To review unanticipated problems and provide an opportunity to refine protocol	• Listing of unanticipated problem reports • Frequency of types of UP's	• PI • Chief of Clinical Protocol • Study Co-Investigators • Research Assistant

There will be no interim analysis performed. Data analysis is detailed in Section 12.4.

15.5 Study Records Retention

Per Rutgers Research Regulatory Affairs, research that involves collection of protected health information (PHI) is subject to the HIPAA regulations. Research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.

15.6 Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the sIRB. Since the purpose of this feasibility study is for protocol refinement, any of the following will not be considered protocol violations unless the subject was put at additional risk as a result of the divergence from the protocol.

- Incomplete visits
- Activities occurring outside of the specified windows
- Missing surveys/forms or data

Upon discovery of a protocol deviation, the Principal Investigator is responsible for reporting protocol deviations to the sIRB.

A protocol violation is a deviation from the sIRB approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data. Protocol Violations must be submitted for Full Board sIRB review. If the deviation meets any of the following criteria, it is considered a protocol violation.

All deviations and violations from the protocol will be recorded on the Protocol Deviation/Violation Reporting Form no later than 10 business days after study staff become aware of the deviation and

forwarded to the study PI for review and reported promptly to the sIRB. All protocol deviations and violations will be reviewed monthly during the PREDICT Steering Committee Meeting.

16 PUBLICATION/DATA SHARING

This study will comply with all applicable NIH Data Sharing Policies. See *https://grants.nih.gov/policy/sharing.htm* for policies and resources.

Dissemination at Scientific Meetings: Presentations at scientific meetings will be delivered to assist in dissemination of results as soon as possible when final results pertaining to the primary variables are available. Meetings at which presentations will be made include, but will not be limited to, American and International Association of Dental Research (AADR and IADR), the American Dental Association (ADA), and International Association for the Study of Pain (IASP) and addiction meetings. NIH grant support will be acknowledged during all presentations.

Publication and Authorship Policies:
Findings will be published in peer-reviewed journals. Journals selected will be indexed in PubMed. Accepted manuscripts will be submitted to PubMed Central as per NIH policy. Examples of journals in which final results may be published include the Journal of Dental Research and the Journal of the American Dental Association. Other medical journals, including journals on pain and addiction will be considered for manuscript publications. Final versions of the peer reviewed manuscripts will be made available to the public, generally within 3 months but no later than 12 months after the official date of publication. NIH grant support will be acknowledged in all publications.

Proposals from study investigators for writing and submitting abstracts and manuscripts for publication will be presented to a committee for approval, comprised of the study PI, chief clinical officer, chief pharmacology officer and chief statistician. Included in the proposal is data needed for the publication, analyses to be performed, proposed authorship and order of authorship, and/or journal in which the manuscript will be published. If a submission for an approved proposal is not completed within 11 months of approval, other authors can submit a similar proposal to the committee for approval.

The following ICMJE guidelines will be adopted and followed in determining authorship:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The National Dental PBRN Publications and Presentations Policy is publicly available at *http://www.nationaldentalpbrn.org/publications/*.

NIH Public Access Policy
The NIH *Public Access Policy* requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to *PubMed Central* immediately upon acceptance for publication. This ensures that the public has access to the published results of NIH funded research.

The PI will share the individual non-identified subject data no later than acceptance for the publication's main findings from the final data analysis or 18 months after completion of the study, whichever is earlier. As NIDCR does not have a data repository at the initiation of this feasibility study, data will be provided to the PBRN resource center who will have the responsibility for posting the data. All study data will be collected in REDCAP with the REDCap project along with all non-identified data collected. The PBRN resource center will convert the data into both SAS and ASCII formats for posting. Data to be posted will include the study protocol and the data set in both SAS and ASCII formats, and data dictionary.

Upon written request to the PI, survey instruments or other materials developed for use during the clinical trial will be made electronically available to other researchers.

17 LITERATURE REFERENCES

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SUPPLEMENTAL MATERIALS

None

APPENDICES

Table of Contents

APPENDIX A1: SCHEDULE OF EVENTS

Dental Health Care Workers

Procedures	Prior to Enrollment Day -28 (+/- 29 days)	Start-of-Study (Baseline) Day 0	Mid-Study Day 14 (+/- 7 days)	End-of-Study Day 28 (+/- 7 days)
Obtain Written Consent	X			
Start-of-Study Survey		X		
Triage Survey		X	X	X
End-of-Study Survey				X
DHCW Participation Questionnaire				X
POC Antigen Test		X	X	X
PCR Viral Test		X		X
ELISA Antibody Test		X		X

APPENDIX B: SCHEDULE OF EVENTS

POC Patient Subject

Procedures	2 Weeks Prior to Visit (Day -14 +/- 14 days)	Day Prior to Visit Day -2 (+/- 2 days)	Visit Day 1
Obtain Informed Consent	X		
POC Antigen Test			X
Triage Survey		X	X
Start-of-Visit Survey	X		
End-of Visit Survey			X
Patient Participation Questionnaire			X
Provision of Dental Care (Not part of study)			X