Title: An Evaluation of Protective Effects of OpalSeal™ Against Early Dental Decay in Orthodontic Patients

NCT #: NCT03722264

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Document Type: Protocol

VCU Office of Research and Innovation
VIRGINIA COMMONWEALTH UNIVERSITY

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ID: HM20011025 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator**
   Parthasarathy Madurantakam

2. * **Study Title**
   An evaluation of protective effects of OpalSeal against early dental decay in orthodontic patients. A pilot study.

[redacted]

[redacted]

ID: HM20011025 View: SF - Research Determination

Research Determination

1. * **Select one of the following that applies to the project**

- (●) **Research Project or Clinical Investigation**
- ( ) Exception from Informed Consent for Planned Emergency Research
- ( ) Humanitarian Use of Device for Treatment or Diagnosis
- ( ) Humanitarian Use of Device for Clinical Investigation
- ( ) Emergency Use of Investigational Drug, Biologic or Device
- ( ) Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- ( ) Center or Institute Adminstrative Grant Review

2. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by your school/center's Research Administration Office**
   - ( ) Yes
   - ( ) No
   - (●) **Not Applicable**

   ***If No above, please contact the appropriate office about completing required coverage analysis documentation for your study. (School of Medicine somct@vcuhealth.org Other Schools/Colleges CRSADM N@vcu.edu)**

ID: HM20011025 View: SF - Federal Regulations

Federal Regulations

1. * **Is this a Clinical Trial? A clinical trial is a study that prospectively assigns human subject(s) to an intervention(s) and evaluates the effects of the intervention on health-related outcomes**
   - (●) **Yes**
   - ( ) No

2. * **Is this a FDA regulated study**
   - (●) **Yes**
   - ( ) No

3. * **Is this study supported by the Department of Defense (DoD)**
   - ( ) Yes
   - (●) **No**

4. * **Check if any of the following funding sources apply to this research**

   None of the above

ID: HM20011025 View: SF - FDA Regulated

FDA Regulated

1. * **Indicate the FDA regulated product(s) this study involves**

   - [ ] Drug
   - [x] **Medical Device**
   - [ ] Biologic
   - [ ] Dietary Supplement
   - [ ] Food/Food Additive
   - [ ] Color Additive
   - [ ] Electronic Products for Human Use (radiation producing)
   - [ ] Other

2. **If "Other" selected above, provide description**

[redacted]

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
[redacted]							

ID: HM20011025 View: SF - Conflict of Interest

Conflict of Interest

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual hold a financial conflict of interest related to this study?**
   - ○ Yes
   - ◉ **No**
2. **If Yes, provide**
   - **Name(s) of the engaged conflicted individual(s)**
   - **Brief description of the financial conflict of interests**
3. * **Describe any potential non-financial conflicts of interest for members of the research team that could impact the conduct of the study (if None, please state "None")**
   None
4. **Describe any institutional conflict of interest with this research that you or any member of the research team may be aware of**

ID: HM20011025 View: SF - Communication Plan for Research Team

Communication Plan for Research Team

1. * **Describe the process that will be used to ensure that all persons at all involved sites assisting with the research are adequately informed about the protocol and their research related duties and functions**
   The PI will ensure that all personnel involved in research will be CITI trained. Team meetings will be held once a week to update progress and address any potential problems that may arise.
   Ad-hoc, in-person meetings with the PI should any special circumstance arise.

ID: HM20011025 View: SF - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review**

- ◉ **VCU IRB**
- ○ Western IRB
- ○ NCI Central IRB
- ○ Other RB

2. **If Other IRB, name the IRB that will review this research. If ORSP has not already agreed to rely on this IRB (via phone or email communication), you are strongly advised to contact IRBReliance@VCU.edu before proceeding with this submission**

ID: HM20011025 View: SF - Review Setup

Review Setup

1. * **Does this study involve greater than minimal risk**
   - ○ Yes
   - ◉ **No**

2. * **Review Type Requested (subject to IRB approval)**

   - ◉ **Full Board**
   - ○ Expedited
   - ○ Exempt

3. * **Has this protocol received a Massey protocol review**
   - ○ Yes
   - ◉ **No**

4. * **Has this human subjects protocol (not the grant application) been reviewed by the funder**
   - ○ Yes
   - ◉ **No**

ID: HM20011025 View: SF - Research Description

Research Description

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Primers are a type of 'glue' routinely used in orthodontics to attach brackets (metallic components) to the teeth. OpalSeal is a fluoride-releasing primer that has the potential to reduce cavities in patients receiving braces.

   Orthodontic patients are at particular risk of developing two types of early carious lesions (decay):
   a. Around the brackets called White Spot Lesions and
   b. Along the sides of the teeth after slenderization procedure called inter-proximal reduction (IPR).

   Our research questions are:
   1. Can OpalSeal offer protection against white spot lesions (WSL) around the brackets?
   2. Can OpalSeal offer protection against decay on the sides of teeth following IPR?

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   We know that fluoride is very effective in preventing dental decay (cavities) when applied in the form of a varnish on tooth surfaces.
   The purpose of this study is to verify if fluoride-releasing primer (OpalSeal) offers more protection against early dental decay (cavity) compared to conventional primer (Transbond XT) during treatment with braces.

3. * **Describe the study's background and significance, including citations, or upload a citation list in document upload. Use lay language whenever possible.**
   Plaque is a sticky, colorless film of bacteria that constantly forms on our teeth that ferments sugars from diet to produce acids. These acids have been shown to dissolve enamel (outermost layer of tooth) that eventually forms a cavity. Having braces increases plaque build up and food accumulation around the brackets (1-2, 4-7), resulting in increased risk for dental decay (cavities).

   The formation of white spot lesions (WSL) is a common risk in patients who undergo orthodontic treatment (1-4), especially those with poor oral hygiene practices (5). The prevalence ranges from 50-96%. WSL represent the early stages of caries (1,3,4) and can form within 4 weeks of the start of treatment (7). The lesions appear white, chalky, and opaque&#65533;and can make the end result of orthodontic therapy very unaesthetic (3,6).

   Fluoride application on the surfaces of teeth has been shown to effectively increase the resistance of enamel to acid attack and reduce decay. Fluoride is currently delivered in a variety of ways: varnishes, gels and mouthrinses (8-11). Fluoride varnish, applied by a dental professional, has been very effective in caries prevention and a similar strategy to deliver fluoride around brackets can potentially prevent WSL.

   The process of gluing brackets onto a tooth involves application of a &#65533;primer&#65533; followed by a resin. Conventional primers do not have fluoride and one such primer (Transbond XT) is routinely used in our patients receiving braces in the Department of Orthodontics. Opal Seal is a recently introduced primer that contains fluoride and has the potential of reducing the incidence of WSL.

   OpalSeal has been approved for clinical use by the FDA and does not present any known risks.
   A recent animal study has shown that Opal Seal significantly reduced the erosive attack of acidic beverages (12).

   PR is a routine procedure employed by orthodontists to treat patients with mild to moderate crowding. IPR is actually a slenderization process that involves abrading away little layers of outermost tooth enamel from the sides of the teeth using hand-held, flexible, diamond-coated abrasive strips. The amount of enamel that we would remove as part of this study is (up to) twice the width of human hair from each side of the tooth.

   PR does not require anesthesia and can be accomplished within 15 minutes. Even though some studies have shown no long term adverse effects of IPR (13,14), others have shown increased plaque accumulation potentially increasing the risk of developing a cavity (15, 16). Our research is interested in evaluating if applying OpalSeal following PR would offer any benefit following IPR.

   (Refer to citation list for numbered references)

4. * **Describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include**
   - **A statement explaining the study design**
   - **A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order**
   - **A description of all research measures/tests/interventions that will be used (if applicable)**
   - **A detailed description or list of all secondary data elements and/or secondary specimens that will be obtained and how they will be used (if applicable)**

See the help text for additional guidance.

Patients at the VCU Orthodontic clinic, 10 years and older, who have consented to for orthodontic treatment (braces) that involves extraction of at least 2 teeth (one on the right and the other on the left side of the mouth) will be approached for participation in the study. Interested participants will be recruited to the study following informed consent process. Dental extraction of teeth as part of orthodontic treatment is typically referred to an oral surgeon and it takes approximately three months to get this procedure. The standard clinical practice in the Department of Orthodontics is to begin treatment right away without waiting for extractions.

Since the teeth planned for extraction are on either side of the mouth, we will use a split-mouth design with random assignments for interventions (OpalSeal). Apart from the intervention, patients will be treated the same way they would be if they were not participating in research. All patients will be given oral hygiene instructions and they will have no additional appointments for research purposes.

Study related interventions will be restricted to teeth that are planned for extraction and will not involve other teeth. These interventions include:
1. Bonding brackets on to-be-extracted teeth, with one receiving OpalSeal
2. Selective grinding of enamel (PR) on to-be-extracted teeth, with one tooth receiving OpalSeal
3. Collection of extracted teeth for laboratory analysis
4. Completion of a short survey

The patient will schedule the extraction appointment with the dentist of their choice (routine clinical protocol) and will update the Orthodontic clinic. Typically, the patients come to the clinic a day or two prior to extraction to get the wires removed (dentists will not extract the teeth with wires still on). At this time, the patient will be given labeled plastic jars containing water and will be instructed to collect the teeth after extractions. The corresponding dentist will be instructed to place the teeth in the jars and hand over the container to the patient. As is the regular protocol, patients will report to the Orthodontic clinic within a few days of extractions to have the wires replaced and continue treatment. Study personnel will collect the jars containing extracted teeth at this follow up appointment.

All specimens will be transferred into 0.1% thymol solution (disinfectant) and stored until analysis. There will be no personally identifiable information on the jars.Samples will undergo the following tests:
a. Scanning electron microscopy to analyze the surface topography
b. Micro-CT to quantify the mineral density
c. Atomic force microscopy to test surface roughness and hardness
d. Fluorescence to quantify the residual amount of OpalSeal

The survey will help us understand how the patient controlled factors affect the incidence of WSL. For example, are right-handed patients more likely to develop WSL on the right side?

"The statistician will generate and provide a computer generated random assignment table to the resident [redacted] The resident will be the only person that will be providing the interventions (OpalSeal or TransbondXT) to the study participants."

1. Bonding brackets on to-be-extracted teeth: Placing brackets on teeth are fundamental to moving teeth and teeth will have a bracket attached at the start of treatment. However, teeth planned for extractions do not receive any brackets in routine clinical practice. In our study though, we will place brackets even on to-be-extracted teeth until they are extracted. Since every patient will have at least two teeth that would be extracted, one of them would receive OpalSeal while the other will receive Transbond XT. The procedures for bonding will be consistent with clinical procedures and protocol for any orthodontic patient treated in the clinic.
2. Administering OpalSeal: OpalSeal will be applied to the teeth of interest following manufacturer's instructions for use (refer to the attached document).
3. Selective grinding of enamel (PR) on to-be-extracted teeth: PR is a deliberate procedure performed on selected teeth to relieve crowding. As a clinical routine, IPR is not done on teeth that are planned for extraction. In our study though, we will do PR on to-be-extracted teeth. Since every patient will have at least two teeth that would be extracted, one will receive OpalSeal after IPR while the other will receive Transbond XT. The PR procedure will involve using a handheld diamond-coated abrasive strips and will use routine diagnostic radiographs to guide the amount of enamel that is shaved off or removed. The procedure will not require any anesthesia and can be accomplished in a few minutes. The amount of enamel removed during this research specific intervention will be similar to what is routinely done in clinical practice, which would be approximately 200 um from two sides of the teeth for all study participants.
4. Completion of a short survey: We would like to have a formal structure to collect pertinent information that can give insights about the effectiveness of OpalSeal to prevent early carious lesions given patient's risk factors. This is not a requirement for required for routine clinical practice. The resident will administer the survey once the patient/parent signs the informed consent document. It will be a paper format and all completed surveys will be stored in the PIs office in a locked cabinet. If the patient has some difficulty in completing the survey, parent's/resident's help will be solicited."

5. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders)**

ID: HM20011025 View: SF - Study Activities

Study Activities

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**

- ○ Bio-Medical
- ○ Qualitative - Social/Behavioral/Education (SBE)
- ○ Quantitative - SBE
- ○ Mixed Method - SBE
- ◉ **Mixed Method - Biomedical**

2. * **This study will involve (check all that apply)**

- ☑ **procedures such as surveys, interviews, field studies, focus groups, educational tests, deception, psycho-physiological testing, any other similar data collection**
- ☑ **secondary data analysis procedures such as analysis of information collected for non-research purposes (includes both retrospective and prospectively collected information), or analysis of data previously collected for a prior research study**
- ☑ **drugs, devices, experimental interventions, biohazards, radiation, other medical or surgical procedures**

ID: HM20011025 View: SF - Bio-Med Project Details

Bio-Med Project Details

1. * **Select all details that apply**

- [ ] Drugs, Biologics, Supplements, and/or Other Compounds
- [x] **Placebo**
- [ ] Washout Period
- [x] **Device Evaluation**
- [ ] Bio-Hazards, Other Toxins, Recombinant DNA/Gene Transfer
- [ ] Radiation Exposure and/or Scans involving radiation (PET, MRA)
- [ ] Stem Cells
- [ ] Expanded Access - Treatment Use of an Investigational Product
- [x] **Other Medical or Surgical Procedures**
- [x] **Protected Health Information (PHI)**

ID: HM20011025 View: SF - Bio-Med Placebo/No Treatment

Bio-Medical Placebo/No Treatment

1. * **Describe and justify the use of placebo**
   Applying primer on a surface of a tooth is a necessary step to achieve optimal bonding of orthodontic brackets. Typical primers used in the clinical practice do not contain fluoride. This study evaluates the effects of a newly introduced fluoride releasing primer (OpalSeal), against a conventional, non-fluoride containing primer (Transbond XT).
   Since Transbond XT does not contain fluoride, it can be considered a placebo.
   Opal Seal and Transbond XT are identical in their color, consistency and application. This ability to blind the participants as well as random assignments will allow us to estimate the true effects of OpalSeal.

ID: HM20011025 View: SF - Bio-Med Device Evaluation Details

Bio-Medical Device Evaluation Details

1. * **Select the type of device evaluation this study will involve**

- [x] **Marketed Medical Device (including 510k device)**
- [ ] Marketed but new indication or intended use
- [ ] Mobile application with regulatory discretion
- [ ] Mobile application without regulatory discretion
- [ ] Investigational device

2. * **List devices this study will involve**

Device	Manufacturer	IDE	IDE Holder	Doc
OpalSeal	Opal Orthodontics	IDE Exempt	Not Required	

3. * **For each device listed above upload documentation of the approved use(s) (operation manual, instructions for use, etc.) or a detailed description of the design, use, and risks of the device**
   - **If 'Investigational Medical Device' or 'New Use for Marketed Medical Device' was selected above AND the device qualifies for IDE exemption under under 21 CFR 812.2(c), upload one of the following documents for each applicable device**
     - **A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c)**
     - **External sponsor's protocol including IDE exemption information**
     - **Communication from the external sponsor verifying the IDE exemption**
     - **Communication from the FDA with verification of IDE exemption**

ID: HM20011025 View: SF - Social/Behavioral Project Details

Social/Behavioral Project Details

1. * **Select all that apply to this study**

- [ ] Analysis of Information Originally Collected for Non-Research Purposes
- [ ] Analysis of Data Originally Collected for a Previous Research Study
- [ ] Behavioral Intervention or Experimentation
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] Population Based Field Study

- [ ] Psychophysiological Testing
- [ ] Deception
- [ ] Oral History
- [ ] Interview/Focus Groups
- [x] **Surveys/Questionnaires/Psychometric Testing**
- [ ] None of the Above

2. * **Will any portion of the research be potentially upsetting to the participants**
   - ○ Yes
   - ◉ **No**
3. **If Yes, describe the nature of the questions and how you will manage the situation should participants become upset**
4. **Upload ALL instruments/guides that will be used, including scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc.**

ID: HM20011025 View: SF - Data Collection Details

Data Collection Details

1. * **Select all involved in the study**

- [x] **Specimen/Biologic Sample Collection**
- [x] **Protected Health Information (PHI)**
- [x] **Secondary Data or Specimens Not From a Registry or Repository**
- [ ] Audio/Video
- [ ] Use of Internet for Data Collection
- [ ] Registries/Repositories (Includes Accessing, Contributing or Creating)
- [ ] None of the Above

2. * **Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized**

- [x] **Names**
- [ ] Geographic Locators Below State Level
- [ ] Social Security Numbers
- [ ] Dates (year alone is not an identifier)
- [ ] Ages >89
- [ ] Phone Numbers
- [ ] Facsimile Numbers
- [ ] E-mail Addresses
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] P Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

3. **If "Other Unique Identifier" was selected above, describe the identifiers**

4. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study if they no longer wish to participate**
   - ○ Yes
   - ◉ **No**

5. **If yes above, describe how participants will be able to withdraw their data**

ID: HM20011025 View: SF - Sample Collection

Sample Collection

1. * **Select all of the types of samples that will be collected as part of this study**

- ☐ Amniotic Fluid
- ☐ Blood
- ☐ Buccal Smears
- ☐ Saliva
- ☐ Tissue
- ☐ Urine
- ☑ **Other**
- ☐ None of the Above

2. **If Other, please describe the type of sample being collected**
   1. Teeth extracted at the time of extraction

3. * **Describe how the samples will be collected and the collection schedule. For each type of sample, include information about**
   - **The procedures that will be followed to collect the sample**
   - **The role(s) of the individuals who will collect the sample**
   - **The volume/size range of the sample**
   - **The timing and frequency of sample collection**

   Conventional Clinical Protocol:
   Patients who require extractions will be referred to an oral surgeon (of their choice) for extraction of teeth. Patients will report to the clinic with the dates of scheduled extractions (with dentists' name and contact information) and they will be seen in the clinic for removal of wires and brackets (from the two teeth that would be extracted). The surgeon cannot remove teeth if the brackets and wires are still in place.
   Within a few days after extractions, the patients will report to the clinic for putting the wires back. This way there is minimal disruption to the orthodontic treatment.

   For study participants:
   When these patients report to the clinic for removal of wires, they will be handed 2 screw-capped plastic jars containing water, clearly labeled right or left for collecting right or left sided teeth. In addition, these jars will also have the initially-assigned, study code, so that the dentist and the patient are blinded to which tooth had OpalSeal. This will not have any PHI that will identify the tooth to the patient by any non-study personnel. The patients will be instructed to hand over the jars to the office staff at the time of extraction. At the end of extraction appointment, the patient will collect the jars (with teeth) and take it home. They will hand over the jars containing the teeth when they return to the clinic to put the wires back on.

   The PI can and will independently verify which tooth had OpalSeal when the samples arrive at the laboratory. This additional step will ensure the collected data is robust and valid.

4. * **Will Genetic Testing be conducted on any of the samples**
   - ○ Yes
   - ◉ **No**

5. * **Will any of the samples be used for a pregnancy test**
   - ○ Yes
   - ◉ **No**

6. **If yes, describe how positive pregnancy results will be communicated to the participant, particularly if minors are involved**

7. * **Will any of the samples be used to screen or document alcohol or illicit drug use**
   - ○ Yes
   - ◉ **No**

8. * **I am aware that I may need to establish a research account with VCUHS Department of Pathology for specimen processing**
   - ◉ **Yes**
   - ○ No

ID: HM20011025 View: SF - H PAA

HIPAA

1. * **Describe the protected health information that will be obtained or used in this research**
   The information that we would collect would include routine patient diagnostic records including radiographs, intraoral photographs as well as treatment plan

2. * **Describe the source(s) of the protected health information**
   We will use patient electronic health records (axiUm and Dolphin) to identify potential study participants.
   Access to these databases is protected by a secure username and password.

3. * **Explain how the PHI collected or used in this research is the minimum necessary to accomplish this research**
   There is no way to prospectively to identify eligible subjects without accessing their medical records. The PHI requested is minimum necessary to identify and recruit potential study participants.

4. * **Select all pathways this research will employ to use or access PHI**

- [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
- [ ] Limited Data Set
- [ ] Waiver of Authorization
- [x] **Partial Waiver of Authorization**
- [x] **Signed Authorization Combined with Consent Form**
- [ ] Signed Authorization as Stand-Alone Form

ID: HM20011025 View: SF - Partial Waiver of Authorization

Partial Waiver of Authorization

1. * **Select the purpose for requesting the partial waiver of authorization**

- [x] **Identify possible participants to recruit for the study**
- [ ] Waive some elements of authorization (such as signature)

2. **If you selected "Waive some elements of authorization" above, list the elements you want to waive and explain why**
We will use Partial Waiver of Authorization to access patients electronic records and identify potential study participants.

3. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy**
All protections of H PAA associated with patient care will also apply for study participants.
Therefore this use of PHI is minimal risk

4. **If you selected "Identify possible participants to recruit" above, describe when will the identifiers be destroyed for those who do not eventually enroll in the study?**

- [ ] Following Participant Contact
- [ ] Following Participant Enrollment
- [x] **Upon Reaching Study Accrual Objectives**
- [ ] Other

5. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
The study team will have the sole access to the PHI

6. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization**
We need access to patients dental records to be able to screen and identify potential study participants.

7. * **In applying for a partial waiver of authorization, the PI agrees to the following**

   - the identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law
   - if at any time the PI wants to reuse this information for other purposes or disclose the information to other indivivdals, the PI will seek approval from the IRB/Privacy Board
   - the PI will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above
   - the PI assumes responsibility for all uses and disclosures of the PHI by members of the study team

(●) **Yes**
( ) No

ID: HM20011025 View: SF - Existing Data/Specimen Details

Existing Data/Specimen Details

1. * **Describe the source and nature of the data/specimens being obtained**
The premolar teeth will be extracted from the participants during the appropriate treatment time. It is important to note that the inclusion criteria for participating in this study includes the need for premolar extractions as per the patient elected treatment plan.

2. * **Describe how you have access to the data/specimens**
The patient will bring in the extracted teeth in the specified containers (with no PHI) and hand them over to the Orthodontic Clinic at the follow up appointment to place the archwires back.

3. *

Describe any identifiers or coded information that will be obtained that can be linked directly or indirectly to the identity of participants

Patients will have a numerical code assigned to them (with no PHI). Extracted teeth will be placed in jars (marked Right or Left) by the staff in the Oral Surgery Clinic and handed over to the patient who will then return these to the Orthodontic clinic. The resident will place the teeth in different jars (labeled with original study code). The key will be available to the study team.

4. * **Did individuals provide consent for research when the data / samples were originally collected?**
(●) **Yes**
( ) No

5. **If yes, did the consent allow for sharing of the data**
(●) **Yes**
( ) No

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared.

1. * **Specify where this study's paper and electronic research data and/or physical specimens will be stored and how they will be secured from improper use and disclosure**

   See the help text for additional guidance.
   All signed informed consent documents and completed surveys will be stored in a locked cabinet in the PI's office. The extracted teeth will be collected in jars containing no PHI from the oral surgery clinic and will be stored in a refrigerator in locked laboratory (Dental Materials Laboratory, Wood Building 101) until analysis.
   In our study, every patient will serve as his/her own control. This is because every patient will have two teeth extracted, one of which will receive OpalSeal and the other, Transbond XT. We will use a computer generated random number table to determine which tooth will receive OpalSeal or Transbond XT. We will generate a code based on:
   a. order of patient enrollment and
   b. whether the tooth received OpalSeal (e) or Transbond XT (c)
   c. date of tooth extraction
   2. This key that links code to the patient will be stored in the PI's office computer that has restricted access (only to study personnel).
   3. The key will be destroyed when the extracted teeth are collected from the patient. Since we would not be needing any PHI, this would decrease the risk of loss of confidentiality.

2. * **Who will have access to study data**
   PI, co-investigator, student researcher, and statistician will have access to the study data. They are all part of the study team.

3. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names with assigned subject IDs, explain the following aspects of the coding process**

   1. **The process for how subject IDs will be generated/assigned (e.g. random, sequential)**
   2. **Whether there will be a key that links the subject ID with direct identifiers.**

      If a key will be created, describe
   3. **The place where the key will be stored**
   4. **The role(s) of all individuals who will have access to the key**
   5. **When the key will be destroyed**

   See the help text for additional guidance.

   The statistician will provide the study team with the computer generated random table. The study participants will be sequentially assigned a 3-digit code followed by R or L (for Right or Left) for OpalSeal. For example, patient 1 may be 001R. The key to the code will be kept by the PI in a password-protected computer and will be destroyed at the end of study.

   We will have 2 codes to simplify the process and decrease confusion:
   The jars handed over to the patients will have fields for date; patient initials; tooth number; Right or Left sides. Patient will be given these jars and will be instructed to hand this over to the staff at the oral surgery clinic who will place the extracted teeth in the correct containers.

   Once the patient hands over the containers (with extracted teeth) to the Orthodontic Clinic, the teeth will be transferred to another jar with the original study codes. The resident and or members of the study team will collect the jars containing the teeth directly from the participant.

4. * **Will the sponsor or investigator obtain a certificate of confidentiality for this study**

   - (●) **No - CoC will not be Obtained**
   - ( ) Yes - CoC has been Obtained
   - ( ) Yes - CoC Request is Pending
   - ( ) Yes - Plan to Submit CoC Request

5. **If the Certificate of Confidentiality has been obtained by the PI, upload it here**

6. * **What will happen to the research records when the research has been completed**

   - ( ) Stored indefinitely with identifiers removed
   - ( ) Stored indefinitely with identifiers attached
   - (●) **Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements**
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

7. **If Other, explain**

8. **If "stored indefinitely with identifiers attached", explain why identifiers are necessary**

Types of Sites

1. * **Select which of the following accurately describes this study**

   - (●) **Not Multicenter Study**

- ○ Multicenter Study - VCU Lead
- ○ Multicenter Study - Non-VCU Lead

2. * **Select all sites where study interventions or interactions will occur and/or identifiable data will be held**

- ☑ **VCU Site**
- ☐ Non-VCU Site (VCU Investigators are conducting/overseeing the conduct of the study)

3. * **Is there a community partner in this research study**
   - ○ Yes
   - ◉ **No**

ID: HM20011025 View: SF - VCU Site Details

VCU Site Details

1. * **Select all VCU sites that will be utilized in this study**

- ☐ Children's Hospital of Richmond at VCU
- ☐ Clinical Research Services Unit (CRSU)
- ☐ Massey Cancer Center
- ☐ VCU Health Community Memorial Hospital
- ☐ VCU Medical Center downtown
- ☐ VCU Monroe Park Campus
- ☐ VCU Qatar
- ☑ **Other VCU Site**

2. * **Provide details regarding each VCU Site including**
   - what clinics / facilities will be used
   - resources that are available for the conduct of this study
   Informed consent and collection of samples (extracted teeth) will occur at the Orthodontic Clinic at VCU School of Dentistry on the MCV campus.
   Once the patient hands over the samples, water will be replaced with 0.1% Thymol solution (disinfectant). Samples in disinfectant will be stored in Dr. Madurantakam's laboratory in the School of Dentistry in a refrigerator until ready for analysis. The samples will be subject to micro CT, AFM at core facilities in the School of Engineering. These samples will not have any personal identifiers and people working with these samples will not know the source (patient information).

ID: HM20011025 View: SF - Study Funding

Study Funding

1. * **Have you applied for funding**
   - ◉ **Yes**
   - ○ No

2. **If so, is this study already funded**
   - ◉ **Yes**
   - ○ No

ID: HM20011025 View: SF - Funding Details

Funding Details

1. * **Select all funding sources for this study (pending or awarded)**

- ☐ Industry
- ☐ Direct Federal
- ☐ Non-Profit
- ☐ Indirect Federal
- ☐ State/Local Government
- ☐ Internal Grant
- ☑ **Investigator/Departmental Funds**
- ☐ None
- ☐ Other

2. **Select all related proposals**

RAMS-SPOT ID# (FP/PT/PD#)	Sponsor	PI	Title	Status	Start	End

There are no items to display

ID: HM20011025 View: SF - Study Population

Study Population

1. * **Provide the total number of individuals at VCU, and at other sites under the VCU IRB, that**
    1. **May participate in any study interaction or intervention (including screening, consenting, and study activities) AND/OR**
    2. **You may obtain any data/specimens about (regardless of identifiability)**

    See the help text for additional guidance.

    35

2. **If this is a multi-Center Project, what is the total anticipated number of subjects across all sites**
    N/A

3. * **Provide justification for the sample size**
    With the number of patients seen in the VCU Orthodontic clinic, this is about the number that we expect to fit into our inclusion criteria. Assuming 80% power and a Wilcoxon rank-sum test, a sample size of 30 would be able to detect a significant difference in the two treatments if 70% of subjects have lower WSL scores on the tooth with Opal Seal (Reference: Noether, G.E. "Sample size determination for some common nonparametric statistics" Journal of the American Statistical Association 82(1987) pp. 645-647).

    We are requesting increased recruitment of 35 to account for some attrition.

4. * **List the study inclusion criteria**
    1) Patients age 10 and older seeking treatment at the VCU Orthodontics Clinic who require extraction of at least 2 teeth for orthodontic purposes
    2) Such teeth should be free of any developmental defects

5. * **List the study exclusion criteria**
    1) Patients under 10 years of age
    2) Patients with defective teeth
    3) Those who cannot provide consent/assent OR not able to follow research protocols
    4) Protected population (prisoners)

6. * **Check all participant groups that will be included in this study or discernable in the research data/specimens. In particular, if you will know that a regulated vulnerable population (children, pregnant women, or prisoners) is involved in the study, be sure to check them**

- [x] **Healthy volunteers**
- [x] **Children**
- [ ] Emancipated minors
- [ ] Pregnant women
- [ ] Fetuses, Neonates, Post-delivery Materials, or In-Vitro Fertilization
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] When cancer is integral to the research - cancer patients, their family members, cancer healthcare providers, or cancer prevention
- [x] **VCU Health System or VCU Dental Care patients**
- [ ] Non-VCU patients
- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [x] **Individuals with limited English proficiency**
- [ ] Active military personnel
- [ ] When researching in a K-12 environment - populations within school districts or other learning environments

7. **Justify the inclusion and exclusion criteria if necessary. If you are either targeting, or excluding, a particular segment of the population / community, provide a description of the group/organization/community and provide a rationale**
    We are not excluding pregnant women from participating in the study. t is common clinical practice to not recommend elective dental procedures during pregnancy. Since orthodontic treatment typically lasts a year and requires follow up every 4-6 weeks, it is uncommon to see pregnant women undergoing active orthodontic treatment.

8. * **Select the age range(s) of the participants who may be involved in this study**

- [ ] < 1 Year
- [ ] 1 - 6 Years
- [x] **7 - 12 Years**
- [x] **13 - 17 Years**
- [x] **18 - 20 Years**
- [x] **21 - 65 Years**

- [x] **> 65 Years**

ID: HM20011025 View: SF - Children

Children

1. * **Check all of the childrens categories that apply to the study**

- [x] **45 CFR 46.404 Research involving no greater than minimal risk to children, with adequate provisions for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408**
- [ ] 45 CFR 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants
- [ ] 45 CFR 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition
- [ ] 45 CFR 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. (Research in this category must be reviewed and approved by the Secretary of the Department of Health & Human Services)

2. * **Will this study involve participants who could be wards of the state**
   - ○ Yes
   - ◉ **No**

3. * **Describe how children will be assented to participate in the study**
   We will identify potential subjects from patients who are accepted for treatment at the VCU Orthodontics clinic. After initial assessment and collecting all diagnostic data, the patient is scheduled for presentation of treatment plan. During this time, the patient and/or parent will be informed about the study.
   After explaining the study at a level that the patient will understand, he/she will be asked if they would like to participate in the study. If the patient agrees to participate and the parent allows it, we will start the informed consent process. If the child does not want to participate in this research, the treatment will proceed as normal.

4. * **Describe how you plan to obtain permission of parents or guardians**
   We will identify potential subjects from patients who are accepted for treatment at the VCU Orthodontics clinic. After initial assessment and collecting all diagnostic data, the patient is scheduled for presentation of treatment plan. During this time, the patient and/or parent will be informed about the study.
   After explaining the study, the parent will be asked if they would like for their child to participate in the study. If the parent agrees to participate, we will start the informed consent process. We will give the ICD for the parent to take home for review and get back for any clarification. During the next appointment (start of braces), signed informed consent will be obtained from the parent. This typically takes around 2 weeks. If the parent does not want their child to participate in this research, the treatment will proceed as normal.

ID: HM20011025 View: SF - Limited English Proficiency

Limited English Proficiency

1. * **Describe how Non-English speaking or limited English proficiency participants will be able to communicate with the study staff at enrollment and throughout the study. Include the following information**
   - **how the initial informed consent process will be handled**
   - **how the research team plans to interact with LEP participants throughout the conduct of the study**
   - **whether there will be a qualified interpreter or assistive translational devices available**
   - **whether the study consent document will be translated or a short form consent document will be used**
   - **the names of the individuals or professional groups who will provide oral interpretation or written translation services**

   We plan to use the short form document for Spanish speakers as we do not anticipate their enrollment greater than 5%. However, should circumstances change, we will use a fully translated consent document which will be submitted to the RB as an amendment prior to implementation. We will use a qualified interpreter (Spanish speaking) employed by the SoD in this process

2. * **Describe any additional risks or harms to the individual because of their limited English proficiency and how these will be minimized**
   There will be no additional risk because we will make sure that informed consent is possible through the appropriate translators and that individuals have the opportunity to ask any questions, the same way they would before undergoing orthodontic treatment at out clinic. Any non-english, non-spanish speakers will be excluded from the study.

3. **If an interpretor or translator will be involved in the study, upload documentation verifying qualifications**

ID: HM20011025 View: SF - Potential Subject Identification and Recruitment

Potential Subject Identification and Recruitment

1. * **Choose all recruitment methods that may be used**

- [ ] E-mail Campaign
- [ ] Phone Solicitation
- [ ] Flyers, Letters or Newspaper/TV/Radio Ads
- [ ] Website
- [x] **Direct Contact**

- [ ] Psychology Research
- [ ] Participant Pool (SONA)
- [ ] VCU TelegRAM announcement
- [ ] Word of Mouth
- [ ] Other

2. If Other, please describe

3. * Select the methods used to obtain names and contact information for potential subjects

- [x] **Pre-Existing Relationship with Participants**
- [x] **Selected from Pre-Existing VCU Records**
- [ ] Selected from Pre-Existing Non-VCU Records
- [ ] Selected from Publicly Available Records
- [ ] Referred by Health Care Provider or Other Health Professional
- [ ] Recruited from Database or Registry
- [ ] Identified through Community Based Organization (Schools, Church Groups, etc.)
- [ ] Self Referred (Flyer/Ad)
- [ ] Other

4. If Other, please describe

5. * Provide a description of

1. **How potential participants or secondary data/specimens of interest will be identified and**
2. **All procedures that will be followed to carry out recruitment and screening activities.**

Include details (as applicable) about

- **How secondary data/specimens that meet the study's eligibility criteria will be identified (i.e. what database(s) will be queried and the search terms that will be used)**
- **How potential participants will be identified and their contact information obtained**
- **The timing and frequency of recruitment activities**
- **Where and how recruitment procedures will be completed**
- **Who will recruit or respond to potential participants**
- **What and how written or verbal recruitment materials and reminders (if any) will be used**
- **What screening activities will occur and how these procedures will be performed**

See the help text for additional guidance.

1. Potential subjects (orthodontic patients requiring at least 2 teeth extractions) will be identified through careful review of EHR at the SoD.
2. It is standard of clinical care to review the treatment plan with every patient/parent and get their consent.
3. We will use this appointment to introduce the patient/ parent to the study and answer any questions regarding their responsibilities.
4. The location for screening and informed consent process will occur in a private patient conference room situated within the Orthodontic Clinic
5. The records will be screened every week to identify potential study participants until the study accrual goals are met
6. The patient/ parent will be given a copy of the informed consent document to take home and discuss with friends and family. Typically it takes 2 weeks between the treatment planning appointment and start of treatment. Eligible subjects will be given this 2-week window to participate in the study. If they do not consent within 2 weeks, the treatment will proceed as planned and they will not be included in the study.

6. Describe any special recruitment procedures for vulnerable populations
The vulnerable population in this study would be children. Since the majority of patients seeking orthodontic treatment are children, this would be consistent with the patient population that is routinely seen in our Orthodontic clinic.
We will use the children seeking care in our clinic for screening and will not make any special recruitment procedures.

7. Upload all recruitment materials including ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders

8. * Before potential participants consent to the study, will screening questions be asked or will any screening procedures/tests be done that would not otherwise be done as standard of care
No

9. If Yes, will identifiable information about individuals be recorded during screening
- ○ Yes
- ○ No

Privacy

1. * Privacy is an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as being asked personal questions in a public setting being publicly identified as having a particular characteristic or diagnosis being photographed, videotaped or observed without consent or disclosing personal information.

Describe how participants' privacy will be protected during
- identification,
- recruitment,
- screening,
- the consent process,

- **conduct of the study, and**
- **data dissemination**

The screening, recruitment and consent procedures will be carried out in a private room located within the orthodontic clinic ensuring complete privacy.
All study related information about the participant will be stored in a secure server in the PI's computer and will not be accessible to anyone other than study personnel. The samples (jars with extracted teeth) will be coded to ensure patient privacy. No personally identifiable information will be attached to the specimens so that no one working in the laboratory will know the source.
Any publications that can arise from this study will protect patient privacy by not disclosing any identifiable information.
Signed informed consent documents will be stored in a locked cabinet in the PI's office.

ID: HM20011025 View: SF - Costs to Participants

Costs to Participants

1. **Select all categories of costs that participants or their insurance companies will be responsible for**

- [x] **Participants will have no costs associated with this study**
- [ ] Study related procedures that would be done under standard of care
- [ ] Study related procedures not associated with standard of care
- [ ] Administration of drugs / devices
- [ ] Study drugs or devices
- [ ] Other

2. **If Other, explain**

3. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
N/A

ID: HM20011025 View: SF - Compensation

Compensation

1. * **Describe any compensation that will be provided including**
- **items such as parking/transportation**
- **total monetary amount**
- **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
- **how it will be disbursed**
Patient/parents will be compensated a total of $25 upon turning over specimens (jars containing 2 extracted teeth) and completing the survey. The compensation will be provided as cash to the parent/patient.

2. **If compensation will be pro-rated, explain the payment schedule**

ID: HM20011025 View: SF - Risks, Discomforts, Potential Harms and Benefits

Risks, Discomforts, Potential Harms and Benefits

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to**

- **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
- **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
- **Research data risks (e.g. loss of confidentiality and privacy)**
- **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
- **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
- **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

See the help text for additional guidance.

1. Risks of bonding brackets: No greater than minimal. Seriousness: minimal Likelihood: unlikely, because, we typically are simultaneously bonding 24 teeth 2. Risk of IPR: Increased sensitivity of the treated tooth to cold and sweets. This can happen if too much tooth enamel is taken away. Seriousness: moderate Likelihood: unlikely 3. Loss of confidentiality. Seriousness: minimal Likelihood: unlikely Risks and side effects of administering Opal Seal include eye irritation, allergic reaction, dermatitis, and rash. Target organ toxicity is not a concern because we use localized, precise delivery systems and no systemic exposure occur.
Risks and side effects of administering Opal Seal include eye irritation, allergic reaction, dermatitis, and rash. Target organ toxicity is not a concern because we use localized, precise delivery systems and no systemic exposure occur.

2. * **Describe how the risks / harms will be minimized**
The risks are usually associated with inappropriate administration and exposure of OpalSeal. OpalSeal is a liquid that is meant for topical application onto the surfaces of the teeth and then polymerized with light. When used this way, there is minimal systemic exposure of the components of OpalSeal and thus the risks are minimized.
Routine standard of care for any patient who develop signs of contact stomatitis is to terminate treatment and referral to allergy clinic for further testing and management. We will follow the same protocol for study participants.
Eye irritation is highly unlikely because of local delivery as well as use of protective eye wear (standard care for all orthodontic patients)
Risks of PR (tooth sensitivity) are minimized because we take approximately 200 um from each side of the tooth, which is less than half the normal thickness of the enamel

Risk of PR:
We will mitigate this risk by carefully reviewing your existing x-rays to measure the amount of enamel prior to PR and identify the safe thickness that can be removed without causing symptoms. The risks are further reduced by the fact that these procedures will be done by experienced specialists.
Risks of PR (tooth sensitivity) are minimized because we take approximately 200 um from each side of the

tooth, which is less than half the normal thickness of the enamel.

Loss of confidentiality:
In order to minimize this risk, all study related procedures will be done by CITI certified professionals. In addition, we will use codes (instead of names) to preserve anonymity of sample specimens and survey responses.
All research related data will be stored in a secure server in the PIs office and its access will be restricted to study personnel.

The risks are usually associated with inappropriate administration and exposure of OpalSeal. OpalSeal is a liquid that is meant for topical application onto the surfaces of the teeth and then polymerized with light. When used this way, there is minimal systemic exposure of the components of OpalSeal and thus the risks are minimized.
Routine standard of care for any patient who develop signs of contact stomatitis is to terminate treatment and referral to allergy clinic for further testing and management. We will follow the same protocol for study participants.
Eye irritation is highly unlikely because of local delivery as well as use of protective eye wear (standard care for all orthodontic patients).

3. **If the disclosure of any of the information obtained during the study would place the individual at risk for harm (legal, reputation, emotional etc.) and the information will be recorded so that the individual could be identified, explain the protections that will be put in place to decrease the risk of disclosure**
   None

4. * **The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect. Is it likely investigators could discover information that would require mandatory reporting by the investigators or staff**
   - ○ Yes
   - ◉ **No**

5. * **Is it likely investigators could discover a participant's previously unknown condition (eg disease, suicidal thoughts, wrong paternity) or if a participant is engaging in illegal activities**
   - ○ Yes
   - ◉ **No**

6. **If yes, explain how and when such a discovery will be handled**

7. * **Describe any potential risks or harms to a community or a specific population based on study findings**
   None anticipated

8. * **Describe criteria for withdrawing an individual participant from the study such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.**
   A patient will be withdrawn from this study if they do not return the specimens (extracted teeth) to the study personnel. In this case, a new patient will be enrolled.

9. * **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns**
   Appearance of visibly openly cavitated lesions would be a criteria for stopping the study

10. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects**
    None anticipated

11. * **Describe any potential for direct benefits to participants in this study**
    The application of Opal Seal is not a direct benefit because the teeth are being extracted.

12. * **Describe the scientific benefit or importance of the knowledge to be gained**
    If the Fluoride containing primer (Opal Seal) is found to be effective at decreasing demineralization of teeth treated with fixed orthodontic appliances, Fluoride containing primers may become the standard of care during orthodontic therapy.

13. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study**
    Whether the patients will participate in the study or not, there will be no effect on the treatment that they would receive at the orthodontic clinic.

14. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP) [Required for all greater than minimal risk studies]**

- ☐ DSMB
- ☐ DSMP
- ☑ **No DSMB/DSMP [Note This response is not applicable for greater than minimal risk studies]**

ID: HM20011025 View: SF - Consent Qualifiers

Consent Qualifiers

1. * **Are you submitting your study as exempt and therefore no consent is required**
   - ○ Yes
   - ◉ **No**

ID: HM20011025 View: SF - Consent Groups

Consent Groups

1. * **List all consent groups**

Group Types	Waivers	Roles	Roles - Other	Consent	Coercion Decision	Re-Consent

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
View	Participant between the ages of 10 to less than 18	Assent by Child or Decisionally Impaired Adult Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult) Short Form Consent (limited applicability)	Waiver of Parental Permission or Legally Authorized Representative Consent Waiver of Assent by Child or Decisionally Impaired Adult Waiver of Some or All Elements of Consent	Principal Investigator Co/Sub-Investigator Trainee/Student		Assent from the child and consent from the parent/guardian will be obtained during the consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision. Typically, this gives patients/parents about 2 weeks.	If any of our participants become adults during the study, they will be re-consented as adults during their next in-office appointment
View	Adult participant	Written/Signed Consent by Participant Assent by Child or Decisionally Impaired Adult Short Form Consent (limited applicability)	Waiver of Parental Permission or Legally Authorized Representative Consent Waiver of Assent by Child or Decisionally Impaired Adult Waiver of Some or All Elements of Consent	Principal Investigator Co/Sub-Investigator Trainee/Student		During their consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision.Typically, this gives patients about 2 weeks.	If adult participants are no longer decisionally impaired, they will be approached with new consent form and new signature obtained during their next in-office appointment

2. Upload any consent / assent documents

ID: HM20011025 View: SF - Waiver of Some or All Elements of Consent

Waiver of Some or All Elements of Consent

Consent groups that require a waiver of some or all elements of consent

Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Status Change
Participant between the ages of 10 to less than 18					Assent from the child and consent from the parent/guardian will be obtained during the consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision. Typically, this gives patients/parents about 2 weeks.	If any of our participants become adults during the study, they will be re-consented as adults during their next in-office appointment
Adult participant					During their consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision.Typically, this gives patients about 2 weeks.	If adult participants are no longer decisionally impaired, they will be approached with new consent form and new signature obtained during their next in-office appointment

The basic elements of informed consent are as follows

1. All of the following:
   - a statement that the study involves research
   - an explanation of the purposes of the research
   - an explanation of the expected duration of the participant's involvement
   - a description of the procedures to be followed
   - identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the participant
3. A description of any benefits to the participant or to others which may reasonably be expected from the research
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled

1. * **Describe which of the elements of informed consent you are waiving or altering for each group listed at the top of this page**
   We request waiving all elements of consent for recruitment in all 3 groups as we would perform chart review before contacting subjects for a formal consent process.

2. * **Will you be waiving parental permission for any of the consent groups at the top of this page**
   - (●) **Yes**
   - ( ) No

3. * **Is this study sanctioned by State and Local Government and designed to study public benefit or service programs**
   - ( ) Yes
   - (●) **No**

ID: HM20011025 View: SF - Waiver of Parental Permission or LAR Consent

Waiver of Parental Permission or LAR Consent

Consent groups that require a waiver of some or all elements of consent

Group	Types	Waivers	Roles - Other	Consent	Coercion	Decision	Status Change
Participant between the ages of 10 to less than 18				Assent from the child and consent from the parent/guardian will be obtained during the consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision. Typically, this gives patients/parents about 2 weeks.	If any of our participants become adults during the study, they will be re-consented as adults during their next in-office appointment
Adult participant				During their consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision.Typically, this gives patients about 2 weeks.	If adult participants are no longer decisionally impaired, they will be approached with new consent form and new signature obtained during their next in-office appointment

1. * **Explain why it is not in the best interest of participants to obtain parental or a Legally Authorized Representative's (LAR) permission and justify the request to waive this permission**
   We request this waiver so that we can conduct chart review before contacting study eligible subjects for a formal consent process.

ID: HM20011025 View: SF - Waiver [45 CFR 46.116d] - Adults

Waiver [45 CFR 46.116d] - Adults

1. * **Explain how the research involves no more than minimal risk to the participants**
   The research is no more than minimal risk to the participants because all protections of HIPAA associated with patient care will also apply for study participants.

2. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants**
   The patient's rights and welfare will not be affected by the chart review and their dental care will not be affected.

3. * **Explain how the research could not practicably be carried out without the waiver or alteration**
   There is no way to prospectively to identify eligible subjects without accessing their medical records.

4. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not**
   After identifying the potential participants, the study team will initiate the informed consent process with the patient/ parent where all study details will be given

ID: HM20011025 View: SF - Short Form Consent

Short Form Consent

Consent groups that require a short form consent document

Groups	Types	Waivers	Roles - Other	Consent	Coercion	Decision	Status Change
Participant between the ages of 10 to less than 18				Assent from the child and consent from the parent/guardian will be obtained during the consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision. Typically, this gives patients/parents about 2 weeks.	If any of our participants become adults during the study, they will be re-consented as adults during their next in-office appointment

Groups	Types	Waivers	Roles - Other	Consent	Coercion	Decision	Status Change
Adult participant				During their consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision.Typically, this gives patients about 2 weeks.	If adult participants are no longer decisionally impaired, they will be approached with new consent form and new signature obtained during their next in-office appointment

1. * **A Short Form written consent stating that the elements of consent have been presented orally to the participant or Legally Authorized Representative 45 CFR 46.117(b)(2).**

   Does the PI certify that all of the following will occur
   1) A witness will be present to observe the consent process
   2) The Short Form will be signed by the participant or the Legally Authorized Representative
   3) The witness will sign both the Short Form and the Summary
   4) The person obtaining consent will sign the Short Form and the Summary
   5) The participant will sign the Short Form
   6) A copy of the Summary and the Short Form will be given to the participant or Legally Authorized Representative

   - (•) Yes
   - ( ) No

2. * **Explain why you are requesting to use a short form consent form**
   We plan to use the short form document for Spanish speakers as we do not anticipate their enrollment greater than 5%. However, should circumstances change, we will use a fully translated consent document which will be submitted to the RB in an amendment prior to implementation. We will use a qualified interpreter (Spanish speaking) employed by the SoD in this process

ID: HM20011025 View: SF - Waiver of Assent by Child or Decisionally Impaired Adult

Waiver of Assent by Child or Decisionally Impaired Adult

Consent groups that require a waiver of assent by child or decisionally impaired adult

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Participant between the ages of 10 to less than 18				Assent from the child and consent from the parent/guardian will be obtained during the consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision. Typically, this gives patients/parents about 2 weeks.	If any of our participants become adults during the study, they will be re-consented as adults during their next in-office appointment
Adult participant				During their consult appointment in a private room at the VCU Orthodontic clinic. Additionally, we will ensure the participants' continued willingness to participate by asking at each visit if they wish to continue with the study. We will stress that there will be no penalty for withdrawing from the study.	Subjects will be told that participation is voluntary, and if they choose not to participate, treatment will not be affected.	Patients will be given up to their bonding appointment (when they get there braces on) to make the decision.Typically, this gives patients about 2 weeks.	If adult participants are no longer decisionally impaired, they will be approached with new consent form and new signature obtained during their next in-office appointment

1. * **Select all categories of participants for which you are requesting a waiver of assent**

   - [x] **Child (children are under the age 18 in VA)**
   - [x] **Decisionally Impaired Adults**

2. * **Select all applicable reasons you are requesting the waiver**

   - [x] **Some or all of the individuals aged 7 or higher (including adults) will not be capable of providing assent based on their developmental status or impact of illness**
   - [ ] The research holds out a prospect of direct benefit not available outside of the research
   - [x] **The participants are capable of assenting and a waiver is being requested according to 45 CFR 46.116(d)**

ID: HM20011025 View: SF - Waiver [45 CFR 46.116d] - Children or DIA

Waiver [45 CFR 46.116d] - Children or DIA

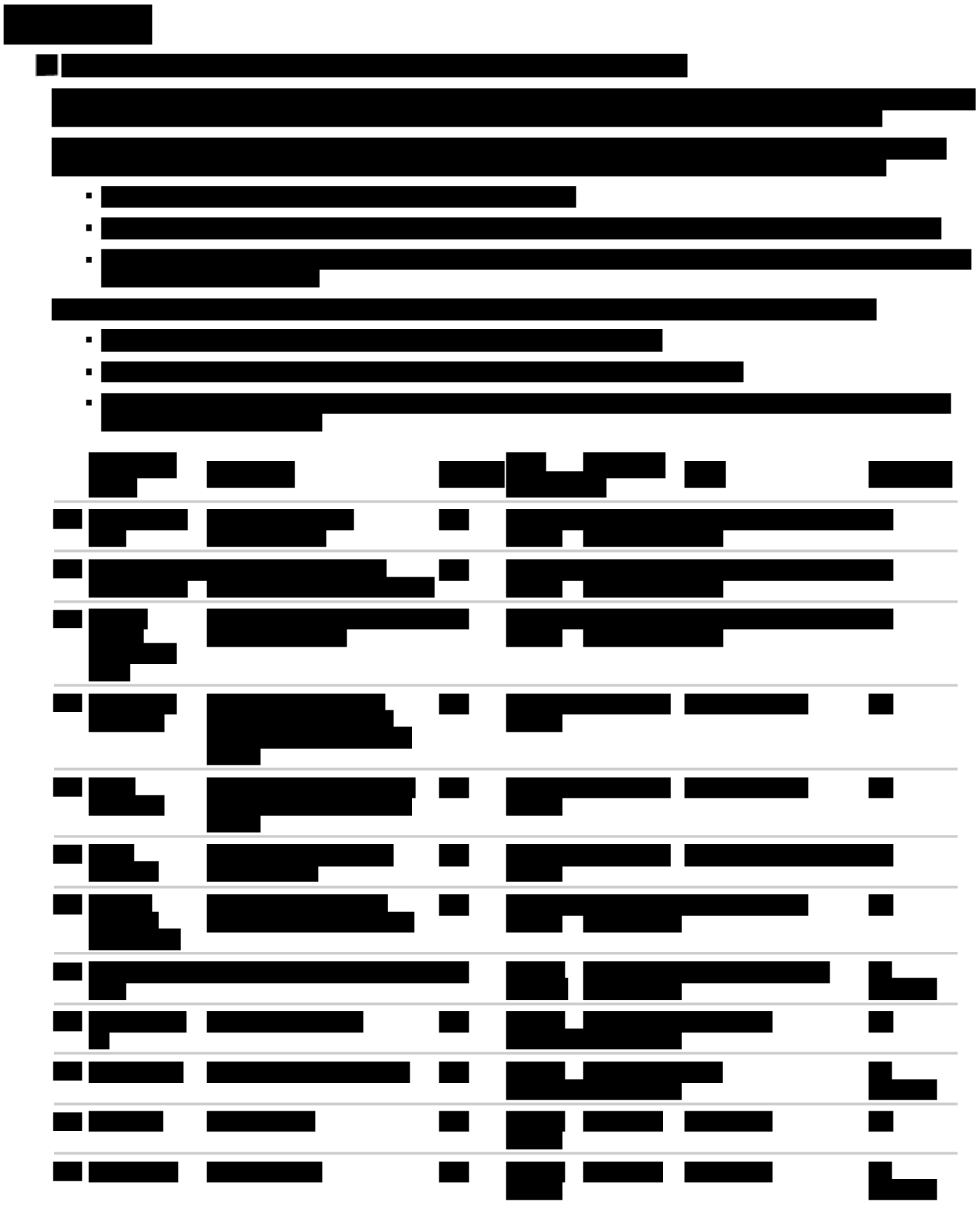
1. * **Explain how the research involves no more than minimal risk to the participants**
   The research is no more than minimal risk to the participants because all protections of HIPAA associated with patient care will also apply for study participants.

2. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants**
The patient's rights and welfare will not be affected by the chart review and their dental care will not be affected.

3. * **Explain how the research could not practicably be carried out without the waiver or alteration**
There is no way to prospectively to identify eligible subjects without accessing their medical records.

4. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not**
After identifying the potential participants, the study team will initiate the informed consent process with the patient/ parent where all study details will be given

[redacted]



Section Complete
SUMMARY

End of Application
IRB HUMAN SUBJECTS STUDY

Click Continue Below

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