VCU Office of Research and Innovation

Date: Tuesday, June 8, 2021 6:34:41 PM Print Close

ID: HM20021396 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Steven Lindauer
2. * **Study Title:**
   The Effect of Aligner Attachment Design on Extrusion of Maxillary Lateral Incisors: a Randomized Prospective Clinical Trial
3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - (●) **Yes**
   - ( ) No

   If this project involves more than one student / trainee investigator, identify the primary contact here and list all student / trainee investigators in the Personnel section. Also ensure all are listed as protocol editors if they need to be copied on IRB correspondence and have authority to make edits.
4. * **Student/Trainee Investigator:**
   Justin Groody
5. * **Please select the primary department or center that this study is being conducted under:**
   Orthodontics
6. **If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:**

ID	Title	PI

   There are no items to display
7. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Carrico	Caroline	ckcarrico@vcu.edu	8048288328	
Groody	Justin	groodyjt@vcu.edu		
Lindauer	Steven	sjlindau@vcu.edu	8048289326	
Madurantakam	Parthasarathy	madurantakap@vcu.edu	8048289353	
Shroff	Bhavna	bshroff@vcu.edu	8048289326	

8. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - (●) **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ( ) Exception from Informed Consent (EFIC) 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 Administrative Grant Review
- ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

ID: HM20021396 View: SF2 - Federal Regulations

Federal Regulations

1. * **Is this a FDA regulated study?**

   FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
   Check Yes if
   • the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,
   • the study involves a test article being administered or dispensed to subjects NOT according to a clinicians• medical judgment but rather, per the study protocol, OR
   • the study does not involve a test article but intends to provide safety or efficacy data to the FDA.

   ○ Yes ● **No**

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

3. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**
   - ☐ Department of Education
   - ☐ Department of Justice
   - ☐ Environmental Protection Agency
   - ☑ **None of the above**

ID: HM20021396 View: SF2 - 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 IRB

2. * **Is this study transitioning to review by another IRB?**
   - ○ Yes - transitioning from VCU IRB to an external IRB (WIRB, CIRB, Other)
   - ○ Yes - transitioning from an external IRB (WIRB, CIRB, Other) to VCU IRB
   - ● **No or not applicable**

ID: HM20021396 View: SF2 - Review Setup

Review Setup

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 Research**
   - ( ) Social/Behavioral/Education (SBE) Research

2. * **Does this study involve greater than minimal risk:**
   No

3. * **Review type requested: (subject to IRB approval):**
   - ( ) Full Board
   - (●) **Expedited**
   - ( ) Exempt

   The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

   The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study.

4. **For Expedited Studies:**

Category 1	Clinical Study of Drugs or Devices	Is a clinical study of A) drugs that do not require an IND or B) devices where an IDE is not required or the device is being used for an approved use.
Category 4	Noninvasive Procedures	Involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves.
Category 5	Nonresearch Data Collection	Involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes including medical treatment or diagnosis.
Category 6	Research Data Collection	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.

ID: HM20021396 View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   Studies on clear aligners (Invisalign) have primarily included case reports, surveys, material studies, expert opinions,

but few clinical trials. Kravitz et al, investigated the efficacy of tooth movement with Invisalign. They evaluated the movements of each tooth individually and concluded that the mean accuracy of movement with Invisalign was 41%. The least accurate movement was extrusion at 29.6%. Krieger et al specifically evaluated anterior tooth position with Invisalign and investigated interarch parameters such as overjet, overbite, and midlines. They concluded that Invisalign successfully corrected anterior crowding, including severe crowding via incisor proclination. Simon et al investigated the effect of attachments and found that premolar rotations were the least accurate movement at 40%.

The 2009 Kravitz et al study reported that maxillary lateral incisors were the teeth that most commonly required extrusion. This was a particularly inaccurate movement with aligners due to the difficulty of the aligners grasping the teeth and pulling them vertically. Boyd described absolute extrusion as being particularly challenging and advocated for the use of a mid-treatment correction such as elastics attached to a button bonded to the facial aspect, or combining extrusion with more predictable movements like lingual constriction or retroclination. Orthodontists have reported 70% to 80% of their aligner patients needing some level of mid-treatment intervention or refinement series to accomplish the goals of the treatment plan.

Though more recent studies have reported improvements in the predictability of most aligner movements, the measured outcomes still fall short of the anticipated changes. Because of the particular difficulties involved with controlling maxillary lateral incisor vertical positioning with aligners, there are many differing expert opinions on how lateral incisor extrusion should be accomplished. Glaser described in his "10 commandments of attachment design", that 4 mm wide gingivally beveled attachments on the maxillary lateral incisors would aid in more accurate extrusive movement. Gomez et al described the initial force systems generated by plastic aligners with and without attachments. They found that attachments created the force systems necessary to bodily tooth movement. Additionally, in a guest editorial in The Angle Orthodontist in 2008, Brezniak claimed that attachments added retentiveness and that extrusion was a difficult movement without attachments due to the clear aligners" tendency to concentrate force in the incisal portion of the teeth. No studies to date have specifically evaluated the challenging movement of maxillary lateral extrusion prospectively, comparing differences in attachment design and determining differences in their effectiveness.

Clinicians can choose any attachment design whether it be the optimized attachments Invisalign provides, a horizontal attachment, or a beveled horizontal attachment, to name a few. A recent study found that orthodontists most frequently chose optimized (17%), rectangular (12%), incisally beveled rectangular (11%) or gingivally beveled rectangular attachments (46%) over other options for enhancing extrusion and that these choices were significantly different from those of general dentists (50%, 22%, 11%, and 3%, respectively). It is up to the clinician, using their expertise, to determine which attachment design best suits the goals of their treatment plan and there are no scientific data currently available. There are a limited number of prospective clinical studies in the literature on any aspects of orthodontic treatment using aligners.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
Question: Which attachment design is most efficacious in extruding maxillary lateral incisor?

   Null Hypothesis: There will be no difference in the efficacy among the four most-commonly used attachment designs (optimized, horizontal, gingivally-beveled horizontal, and incisally-beveled horizontal extrusion attachments) in extrusion of maxillary lateral incisor.

   The goal of the study is to evaluate efficacy of different attachments and not their effectiveness on lateral incisor extrusion.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The aim of this prospective, randomized controlled trial is to determine which of the four different attachment designs (optimized, horizontal, gingivally-beveled or incisally-beveled) offers more predictable extrusion of maxillary lateral incisors in patients treated with clear aligners (Invisialgin, Align Technologies, Inc, USA). The secondary objective is to evaluate the accuracy of ClinCheck software in predicting the three-dimensional final position of the lateral incisor following extrusion using the attachment designs tested. The purpose is to be able to provide clinically-relevant recommendations for attachment planning for extrusion of maxillary lateral incisors during aligner treatment.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   Maxillary lateral incisor extrusion is one of the least effective movements with clear aligners. Orthodontists and general dentists using their expertise can design clear aligner attachments how they see fit for the particular tooth movement they are trying to achieve. Currently there is no evidence in the literature that compares the efficacy of different attachment designs for maxillary lateral extrusion. There is however, anecdotal evidence based on clinician experience regarding which attachment is more efficacious different experts tout different designs. This study will serve as a guide for clinicians to design the best attachment for the most effective and predictable extrusion of the maxillary lateral incisor. More predictable and effective lateral extrusion will limit the need for midcourse intervention for patients and that will result in less appliances and treatment time.

5. * **Describe any potential for direct benefits to participants in this study:**
Although all attachments are known to be somewhat effective in lateral incisor extrusion, patients in one arm of the study may benefit more from the use of specific type of attachment that was randomly assigned to that group.

6. **Upload a supporting citation list if applicable:**

ID: HM20021396 View: SF2 - Study Population

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   80

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   The maximum anticipated number of subjects is 80.

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   A power analysis was used to determine the need for 20 maxillary lateral incisors for each of the four attachment design groups.
   Based on data from prior publications, the common standard deviation for extrusion was assumed to be 1.25. When the sample size is 15, a one-way repeated measures analysis of variance with a 0.05 significance level will have 80% power to detect a difference in means across the 4 groups of the repeated measures factor characterized by an effect size of 0.199 (based on a Variance of means, V=?(�?-�)�/M, of 0.156, a standard deviation at each level of 1.25, and a between level correlation, ?, of 0.5).
   Increasing the sample size to 20 per group would have power to detect an effect size of 0.146 and variance of means of 0.114. These estimates reflect small effect sizes 15 and therefore would be able to detect clinically meaningful differences in the extrusion of the 4 attachments. Sample size calculations estimated with nQuery v8.5.2 (Statistical Solutions Ltd 2020).

4. * **List the study inclusion criteria:**
   (1) Patients 16 years or older to be treated with either Comprehensive Invisalign or Invisalign Teen,
   (2) Maxillary lateral incisor requiring 0.3 mm or more extrusion (as determined by ClinCheck),
   (3) Maxillary arch with less than 6 mm of crowding or spacing,
   (4) All teeth present and fully erupted (excluding third molars).

5. * **List the study exclusion criteria:**
   (1) Presence of anterior crossbite
   (2) Any missing teeth in the maxillary arch
   (3) Treatment plan includes surgery or extraction of any maxillary teeth,
   (4) Maxillary lateral incisors with pathology or large restorations (crowns)
   (5) Maxillary lateral incisors have a less than 0.3 mm of extrusion prescribed in the Tooth Movement Table on the Invisalign ClinCheck

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - (●) **Included**
   - ( ) Excluded - safety concerns if participants are unable to communicate with the study team
   - ( ) Excluded - instruments/measures only validated in English
   - ( ) Excluded - no prospect of direct benefit to individual participants
   - ( ) Excluded - minimal risk study
   - ( ) Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
   - ( ) Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria 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 targeting patients seeking orthodontic treatment with clear aligner therapy. These inclusion and exclusion criteria are to ensure a proper study design.

ID: HM20021396 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Study Procedures

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Question: Which attachment design is most efficacious in extruding maxillary lateral incisor?

   Null Hypothesis: There will be no difference in the efficacy among the four most-commonly used attachment designs (optimized, horizontal, gingivally-beveled horizontal, and incisally-beveled horizontal extrusion attachments) in extrusion of maxillary lateral incisor.

   The goal of the study is to evaluate efficacy of different attachments and not their effectiveness on lateral incisor extrusion.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aim of this prospective, randomized controlled trial is to determine which of the four different attachment designs (optimized, horizontal, gingivally-beveled or incisally-beveled) offers more predictable extrusion of maxillary lateral incisors in patients treated with clear aligners (Invisialgin, Align Technologies, Inc, USA). The secondary objective is to evaluate the accuracy of ClinCheck software in predicting the three-dimensional final position of the lateral incisor following extrusion using the attachment designs tested. The purpose is to be able to provide clinically-relevant recommendations for attachment planning for extrusion of maxillary lateral incisors during aligner treatment.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
   - ☐ E-mail invitations
   - ☐ Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
   - ☐ Flyers, Mailed Letters or Newspaper/TV/Radio Ads
   - ☐ TelegRAM announcements
   - ☐ Website text
   - ☐ Study-specific web sites (provide the design and text)
   - ☐ Social Media
   - ☐ Psychology Research Participant Pool (SONA) study descriptions
   - ☐ Scripts for announcements made to groups
   - ☐ Other recruitment material
   - ☑ **No recruitment materials**

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address the following three aspects of recruitment in your response.**

   1. Identification of potentially eligible participants or secondary data/specimens of interest.
   - What database(s) will be queried to identify secondary data/specimens

- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
1. Patients in this study will be recruited from:
a. Department of Orthodontics at Virginia Commonwealth University using axiUm, the electronic health record
b. Two private practice offices (Richmond and Chantilly) in Virginia. These practices own and manage their EHR which will be used to identify potential study participants. Both private practice orthodontists are rated as VIP Diamond plus providers by Invisalign (meaning they are among the top providers of this treatment nationwide) and one of them is also an adjunct faculty who supervises most of the aligner cases treated at VCU.

2. Since the potential participants are those who actively seek orthodontic treatment at any one of these three locations, we would have the contact information and no additional recruitment methods would be used.

3.
a. Routine clinical practice: All potential patients seeking orthodontic treatment will have an initial consultation appointment with the orthodontist. At this appointment, the orthodontist will have an opportunity to assess patient needs/ expectations as well as conduct an examination to present viable treatment options to the patient. All patients will also have their teeth and gums scanned by an intraoral scanner. This information is sent to Align Technology whose proprietary software (ClinCheck) is used to design and engineer a sequential set of trays that would progressively move teeth to their ideal positions in the mouth. ClinCheck software also provides the quantitative estimate of the magnitude of tooth movement required (in tenths of mm) as well as its direction (in degrees). Together, this information is used to design the clear aligners.

b. Study related screening:

During this consultation appointment, the patients will be evaluated to see if they meet the stated exclusion criteria (missing teeth in maxillary arch; lateral incisors with pathology/ restorations, treatment plan include extractions, presence of anterior cross bite, need for maxillary lateral incisor extrusion) to screen out ineligible study participants.

All patients who do not meet the exclusion criteria will be considered potential study participants and will be informed of the study and requested to participate and consent obtained. Their teeth and gums will be scanned as indicated under routine clinical care and the final inclusion will be determined based on the report generated by ClinCheck (>0.3mm lateral incisor extrusion and <6mm crowding). The time gap between intraoral scanning and generation of ClinCheck is a few days and getting the consent for all non-excluded participants is proposed out of respect for patient/ doctor's time because it precludes a need for a separate appointment (just to get consent) and improves efficiency.
It will be explained to the patient that they could be excluded from the study if analysis of ClinCheck software data indicates their ineligibility (required lateral incisor exclusion <0.3mm and crowding >6mm). Such patients would be considered screening failures.

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

○ Yes

● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. A description of all research measures/tests/interventions that will be used (if applicable)

See the help text for additional guidance
1.
Randomized Controlled Trial.
The biostatistician on the study team (Dr. Carrico) will generate random sequence in blocks of 4 using a computer. All study participants will be assigned a unique identifier (4 digit code) generated by the study team based on order of enrollment and the type of attachment. The key that links code to the patient will be stored in the PI's office computer that has restricted access (only to study personnel). The key will be destroyed when the study is completed.

2.

Members of the study team including residents, Drs. Kravitz and Gardner will have a meeting prior to start of the study to calibrate on the screening criteria to determine eligibility as well as obtaining signatures and maintaining the consent documents. The team will also have a virtual meeting over zoom at least once a month to update on study progress.

All members of the study team will inform Dr. Groody when a study participant is recruited to the study through a secure email. Dr. Groody will then communicate the randomly assigned attachment design to the treating orthodontist based on the sequence generated by Dr. Carrico. The treating orthodontist will then put this information as an order to Align Technology for the fabrication of the attachment trays and clear aligners.

During the scheduled appointment for the delivery of aligners, the patients will be instructed on how to properly place and remove aligners and their maintenance. Patients will be instructed to wear each aligner for a minimum of 22 hours a day for 7 days. Participants will verbally confirm compliance at each appointment. At the end of a series of 20-25 aligners, another intraoral scan will be taken and sent to Align Technologies to determine the final positions of the teeth. Comparison of initial and final positions (using Geomagic software) will be done to assess the efficacy of different types of attachments in lateral incisor extrusion.

Once the teeth are in desired positions, the treating orthodontist will remove the attachment (<6 months).

3.
Research related interventions include:
a. random assignment of the specific type of attachment on lateral incisor;
b. treating orthodontist placing the corresponding order in the prescription with Align Technology;
c. delivery of attachments and aligners to the study participants
d. Superimposition of final and initial positions of lateral incisors: Two superimpositions will be completed. The pretreatment model will be superimposed with the predicted final model to establish the predicted movement of the maxillary lateral incisors. The pretreatment model will be superimposed with the posttreatment model to establish the actual movement of the maxillary lateral incisor. The actual and predicted movement values will be calculated by the GeoMagic software. The amount of extrusion for the lateral incisors will be analyzed in increments of 0.1 mm.

Sample size: 80 maxillary lateral incisors with at least 20 teeth per study group. Randomization will occur at the level of individual lateral incisor tooth.

Study Duration: Patients will be evaluated only after the first series of aligners (20-25). Each set of aligners would be worn for a week and the study would span 20 - 25 weeks.

7. * **The IRB only reviews research activities, so indicate which of the study activities are:**

- Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
- Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
- Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
Research related interventions include:
a. random assignment of the specific type of attachment on lateral incisor;
b. treating orthodontist placing the corresponding order in the prescription with Align Technology;
c. delivery of attachments and aligners to the study participants
d. Superimposition of final and initial positions of lateral incisors: Two superimpositions will be completed. The pretreatment model will be superimposed with the predicted final model to establish the predicted movement of the maxillary lateral incisors. The pretreatment model will be superimposed with the posttreatment model to establish the actual movement of the maxillary lateral incisor. The actual and predicted movement values will be calculated by the GeoMagic software. The amount of extrusion for the lateral incisors will be analyzed in increments of 0.1 mm.

In clinical practice (as in this study) it is nearly always needed to take an intraoral scan at the end of the first set of aligners. This is an optical scanning of the mouth and has no additional risks associated with it. In this study, the scan will be used to assess the results of the randomized intervention. For practice purposes, it is used to construct retainers (if the treatment is done) or, more commonly, to construct an additional set of aligners to continue treatment and improve the result for the patient.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
They can choose to continue to receive the Invisalign care without being a part of the study. They will not be randomized and the treating orthodontist will choose the type of attachment based on clinical judgment and experience.

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

Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts,

letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

ID: HM20021396 View: SF2 - Project Details

Project Details

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [ ] Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations
   - [ ] Deception (misleading participants through false or incomplete information)
   - [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, and HUDs used in clinical investigations
   - [ ] Washout Periods
   - [ ] Expanded Access - Treatment Use of an Investigational Product
   - [x] **Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)**
   - [ ] Specimen/biological sample collection
   - [ ] None of the Above

2. * **Select all of the following types of interactions that apply to this study (selections will branch):**
   - [ ] Surveys / Questionnaires /Written responses to questions (including data entry)
   - [ ] Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [x] **Audio / Video recording or photographing participants**
   - [ ] Observations
   - [ ] Passive Internet data collection (i.e. passively observing online behavior)
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **Select all types of recordings that will be made:**
   - [ ] Audio
   - [ ] Video
   - [x] **Photographs**

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
   All participants will have their teeth scanned before start of treatment and at the end of first series of aligners using iTero intraoral scanners.
   These are standard of care for Invisalign and are not specific to the conduct of research.
   No identifiable information (face) will be captured in these scans. It is only the pictures of teeth within each jaw that will be imaged/ scanned.

5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**
   - [x] **Individually Identifiable Health Information (PHI or RHI)**
   - [ ] Secondary data/specimens NOT from a research registry or repository
   - [ ] Information/specimens from a research registry or repository (Usage Protocol)
   - [ ] Information/specimens originally collected for a previous research study

- ☐ Publicly available information/specimens
- ☐ Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- ☐ No secondary data/specimens will be used

ID: HM20021396 View: SF2 - Secondary Data/Specimen Details

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   1. Patient demographic information (age, sex and race) will be collected from the EHR.

   2. The initial consultation appointment will include documentation of patient's clinical condition, orthodontic diagnosis & treatment plan as well as patient expectations. These are routinely entered as part of clinical notes in the EHR.

   3. Intraoral scans using an optical scanner will be done at 2 time points: at the start to determine study eligibility (required lateral incisor extrusion >0.3mm and crowding <6mm) and at the end of first series of aligners (5-6 months after start of treatment) to determine the final positions of lateral incisors. The digital model of the maxillary and mandibular teeth will be stored in password-protected file. This file will be de-identified before analysis.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   there is no agreement between us and the data provider

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - ○ Yes
   - ● **No**

ID: HM20021396 View: SF2 - Costs to Participants

Costs to Participants

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

ID: HM20021396 View: SF2 - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**

   Every lateral incisor that requires extrusion and qualifies for the study will be compensated with a $50 gift card. The compensation will be distributed to study participants in person when they complete the second intraoral scan at the end of their initial series of clear aligners. Since there are two lateral incisors, a study participant's potential compensation can be $100 if both their lateral incisors qualify for the study.

2. **If compensation will be pro-rated, explain the payment schedule.**
   Compensation will not be pro-rated.

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - (●) **Yes**
   - ( ) No

ID: HM20021396 View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Consent Process

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
View	Consent	Signed Consent by Participant Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent Short Form Consent (limited applicability)	No Waivers Requested Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)	Other Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator Trainee/Student(working on project)	dental assistants who support the clinic operations	Consent process will start when treating orthodontists/ residents deem the patient may be eligible based on established inclusion/ exclusion criteria. Any member of the study team will present the research	All potential participants wilfully seek orthodontic care at any of the three study locations. These subjects choose to become patients after the initial consultation appointment. There is no pre-existing relationships	They would be given 2 weeks to make a decision.	This is a short term study that will last a maximum of 6 months. In the unlikely situation that the participant enters adulthood at any stage of the study (while actively on the first series of aligners or during data analysis), we will reconsent

study in detail in a semi private room in the treating orthodontic clinic to potential participants. If the patient agrees to participate in the study, the consent document document will be presented and their signature obtained. If the participant is not an adult, the conversation will include the parent/ legal guardian and their signatures obtained. Children assent will be obtained when appropriate	between the treating resident / orthodontist and the potential patient. In this sense, study participants are no different from any other patient. In any case, the study team will make it clear to the potential participant that the participation is completely voluntary and non-participation will not affect the intended treatment in any way.	him/her using the adult consent document. Even though the study itself lasts only 6 months, the comprehensive orthodontic treatment would take much longer (12-18 months). In a vast majority of cases, incisor correction is done at the start and we expect all data analysis to be completed within a few months after the second scan. There are 2 possibilities when the issue of reconsenting arise: a. If the participants turns 18 while they are still on aligner therapy (irrespective of whether they are on initial series or beyond): In these cases, the study team will have an opportunity to see the participant in person for routine follow-up and will re-consent in person b. In the rare instance where the patients are off aligner therapy when data analysis is still in progress, the study team will reach out to the participant over phone and will seek reconsenting. We have checked the box for waiver of documentation of reconsent.

2. Upload any consent / assent documents:

ID: HM20021396 View: SF2- Waiver of Documentation of Consent

Waiver of Documentation of Consent

Consent groups that require a waiver of documentation (i.e. consent form not signed):

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
Consent	Signed Consent by Participant Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent Short Form Consent (limited applicability)	No Waivers Requested Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)	Other Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator Trainee/Student(working on project)	dental assistants who support the clinic operations	Consent process will start when treating orthodontists/ residents deem the patient may be eligible based on established inclusion/ exclusion criteria. Any member of the study team will present the research study in detail in a semi private room in the treating orthodontic clinic to potential participants. If the patient agrees to participate in the study, the consent document will be presented and their signature obtained. If the participant is not an adult, the conversation will include the parent/ legal guardian and their signatures obtained. Children assent will be obtained when appropriate	They would be given 2 weeks to make a decision.	This is a short term study that will last a maximum of 6 months. In the unlikely situation that the participant enters adulthood at any stage of the study (while actively on the first series of aligners or during data analysis), we will reconsent him/her using the adult consent document. Even though the study itself lasts only 6 months, the comprehensive orthodontic treatment would take much longer (12-18 months). In a vast majority of cases, incisor correction is done at the start and we expect all data analysis to be completed within a few months after the second scan. There are 2 possibilities when the issue of reconsenting arise: a. If the participants turns 18 while they are still on aligner therapy (irrespective of whether they are on initial series or beyond): In these cases, the study team will have an opportunity to

see the participant in person for routine follow-up and will re-consent in person b. In the rare instance where the patients are off aligner therapy when data analysis is still in progress, the study team will reach out to the participant over phone and will seek reconsenting. We have checked the box for waiver of documentation of reconsent.

1. * **Select which of the following applies to the consent groups used in this study:**
   - [x] **(1) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern**
   - [ ] (2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context
   - [ ] (3) The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

2. * **Explain how your selection above applies to this study:**
   We are requesting this waiver only in the specific context of reconsenting in participants who have completed their aligner therapy and turn 18 when data analysis is still in progress. In this circumstance, the participant no longer returns to the orthodontic office and reconsenting would only increase the potential breach of confidentiality.
   We expect this to be a very rare occurrence given that the study is:
   a. only 6 months long
   b. Incisor extrusion is carried out at the start of treatment and
   c. Completion of aligner therapy may take 12-18 months

ID: HM20021396 View: SF2 - Short Form Consent

Short Form Consent

Consent groups that require a short form consent document:

Groups	Types	Waivers	Roles	Roles Other	Consent	Decision	Status Change
Consent	Signed Consent by Participant Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)	Other Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator Trainee/Student(working on project)	dental assistants who support the clinic operations	Consent process will start when treating orthodontists/ residents deem the patient may be eligible based on established inclusion/ exclusion	They would be given 2 weeks to make a decision.	This is a short term study that will last a maximum of 6 months. In the unlikely situation that the participant enters adulthood at any stage of the study (while actively on the

Short Form Consent (limited applicability)		criteria. Any member of the study team will present the research study in detail in a semi private room in the treating orthodontic clinic to potential participants. If the patient agrees to participate in the study, the consent document document will be presented and their signature obtained. If the participant is not an adult, the conversation will include the parent/ legal guardian and their signatures obtained. Children assent will be obtained when appropriate	first series of aligners or during data analysis), we will reconsent him/her using the adult consent document. Even though the study itself lasts only 6 months, the comprehensive orthodontic treatment would take much longer (12-18 months). In a vast majority of cases, incisor correction is done at the start and we expect all data analysis to be completed within a few months after the second scan. There are 2 possibilities when the issue of reconsenting arise: a. If the participants turns 18 while they are still on aligner therapy (irrespective of whether they are on initial series or beyond): In these cases, the study team will have an opportunity to see the participant in person for routine follow-up and will re-consent in person b. In the rare instance where the patients are off aligner therapy when data analysis is still in progress, the study team will reach out to the participant over phone and will seek reconsenting. We have checked the box for waiver of

documentation of reconsent.

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:**
   Traditionally the orthodontic patients in the clinic is around 2% and so we intend to sue the short form. If the number of LEP subjects approaches the recommended threshold of 5%, we will submit a fully translated consent document to the IRB as an amendment and will not enroll LEP participants until we get IRB approval.

ID: HM20021396 View: SF2 - Consent Plan Complete

Consent Plan Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

Risks, Discomforts, Potential Harms and Monitoring

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.

The study is a no greater than minimal risk in terms of physical/ psychological risk. Even though we are investigating different attachments, all of these 4 variations routinely employed in clinical practice. There is no evidence that one attachment is more harmful (plaque retention, staining, bond failure or patient comfort) compared to others. Attachments will be bonded to teeth following routine clinical protocols.

Privacy risk will be minimized by screening and recruiting potential participants in a semi private office space. We will reduce the risk of loss of confidentiality by maintaining the research data in VCU approved storage devices that only members of the study team can access. It will be password protected.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   The study is a no greater than minimal risk in terms of physical/ psychological risk. All the treatment provided is routine clinical care. Privacy risk will be minimized by screening and recruiting potential participants in a semi private office space. We will reduce the risk of loss of confidentiality by maintaining the research data in VCU approved storage devices that only members of the study team can access. It will be password protected.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   None

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   Inability to comply with the protocol (missing dental appointments, poor compliance with regards to Invisalign wear and bad oral hygiene)
   Determined to be ineligible for the study as determined by ClinCheck analysis as part of screening

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   None

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **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: HM20021396 View: SF2 - Privacy

Privacy

Privacy refers to 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 seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality

protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. Not all will be applicable to every study.

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [x] **Asking the participant if they are comfortable answering questions in that location**
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**
   - [ ] Moving away from other people when conducting activities in public spaces or offering a private space
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Other protections not listed in this question " describe below
   - [ ] N/A " study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
   - [ ] Allowing participants to use a pseudonym or limiting use of individuals" names during the group activity
   - [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
   - [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
   - [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
   - [ ] Allowing people to distance themselves from other participants during group activities
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Ensuring non-participating individuals are not captured on recordings or in photos
   - [ ] Other protections not listed in this question " describe below
   - [x] **N/A " study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, video-conference, tele-health, online, etc.):**
   - [ ] Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)
   - [ ] Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.

- [ ] Obtaining permission prior to sending text messages
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] Offering a way to save and return later to the online activity if privacy is compromised
- [ ] Other protections not listed in this question describe below
- [x] **N/A study has no remote interventions or interactions with participants**

4. * **Protections when mailing study materials to/from participants:**
   - [ ] Obtaining permission to mail study materials
   - [ ] Confirming/verifying the accuracy of addresses before mailing items
   - [ ] Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)
   - [ ] Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.
   - [ ] Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)
   - [ ] Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address
   - [ ] Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer
   - [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
   - [ ] Other protections not listed in this question describe below
   - [x] **N/A not mailing any materials to/from participants**

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:
   - [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
   - [ ] Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)
   - [ ] Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform
   - [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
   - [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
   - [ ] Other protections not listed in this question describe below

6. * **If other protections was selected in one or more of the questions above, describe all the other way(s) that the research team will protect participants' privacy. See the help text for additional guidance.**
   None

ID: HM20021396 View: SF2 - Data Confidentiality and Storage

Data Confidentiality and Storage

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

maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - ☐ Maintaining control of paper documents at all times, including when at an off-campus location
   - ☐ Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)
   - ☐ Storing paper documents in a secure location accessible only to authorized study personnel
   - ☐ Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy
   - ☐ Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies
   - ☐ Other protection not listed in this question – describe below
   - ☑ **N/A – no paper research materials**

2. * **Protections for research specimens:**
   - ☐ Maintaining control of specimens at all times, including when at an off-campus location
   - ☐ Storing specimens in a secure location accessible only to authorized study personnel
   - ☐ Labeling specimens with subject ID or other coded information instead of direct identifiers
   - ☐ Final destruction of specimens will be devoid of any identifiable information
   - ☐ Other protection not listed in this question – describe below
   - ☑ **N/A – no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - ☑ ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - ☐ Remotely accessing VCU network storage to store data when at off-campus locations
   - ☑ **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - ☐ Using VCU-approved data collection tools and apps (i.e. REDCap, Qualtrics) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)
   - ☐ When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps): – consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/); – advising participants about the terms of use and privacy policies of those sites/apps; – limiting or avoiding use of identifiers; and – removing data promptly from the external location after transferring it to a VCU storage location
   - ☑ **De-identifying the research data by replacing subjects' names with assigned subject IDs**
   - ☑ **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - ☐ When analyzing particularly sensitive information, using computers that are unconnected from the internet.
   - ☐ Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies
   - ☐ Other protection not listed in this question – describe below

4. * **Protections for computers and research devices/apps provided for participant use by the study:**
   - ☐ Transferring data promptly from the device/app to a VCU storage location
   - ☐ Setting strong passwords on computers and research devices (when applicable)

- [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
- [ ] Other protection not listed in this question describe below
- [x] **N/A no computers or devices/apps being provided for participant use**

5. * **Protections for email/online communications**
   - [ ] Only using VCU/VCU Health email addresses for study-related communications
   - [ ] Only using VCU/VCU Health approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)
   - [ ] Other protection not listed in this question describe below
   - [x] **N/A no email/online communications**

6. * **If "other protections" was selected in one or more of the questions above, 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.**
   None

7. * **If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team or the PI's department, identify the data recipient(s) along with their VCU department or other institutional or organizational affiliation(s).**
   N/A

8. * **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 over 89 (age under 89 is not an identifier)
   - [x] **Phone Numbers**
   - [ ] Facsimile Numbers
   - [x] **E-mail Addresses**
   - [x] **Medical Record Numbers**
   - [ ] Device Identifiers
   - [ ] Biometric Identifiers
   - [ ] Web URLs
   - [ ] IP 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#

9. * **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:**

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

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

See the help text for guidance.
The study is a 4-arm randomized trial. Subjects will be screened for eligibility based on inclusion/ exclusion criteria. Once informed consent is obtained, the participants will be randomly assigned to one of the four attachment designs. The biostatistician on the study team (Dr. Carrico) will generate random sequence using a computer. The randomization will be in block of 4 and the list will be provided to the study team.

All study participants will be assigned a unique identifier (4 digit code) generated by the study team based on order of enrollment and whether they received horizontal, incisally bevelled, gingivally bevelled or optimized attachments. 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). The key will be destroyed when the all participants complete their second scan (data collection is complete).

All data records used for analysis will have this assigned code without any identifying information. This will minimize the amount of recontacting needed for children who turn 18 during data analysis stage.

ID: HM20021396 View: SF2 - Data Retention

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - ☐ Immediately destroy the information and identifiers (no data collected)
   - ☐ Immediately destroy the identifiers connected with the data (anonymization)
   - ☐ Store until the end of study & then destroy
   - ☐ Use as "screening failure" data by members of the study team
   - ☐ Provide to others outside of the research team (with the participant's permission)
   - ☐ Request permission from participant to maintain and use the identifiable information
   - ☐ Other
   - ☑ **N/A - study does not require screening procedures**

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No - see help text)**
   - ○ Yes
   - ● **No**

3. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) 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

4. * **Will audio/video recordings and full face photographs be destroyed?**

- ○ Yes
- ● **No**

5. **If yes, describe at what point and how recordings will be destroyed:**

6. **If no, explain why the recordings need to be maintained:**
   There are no audio or video recordings in this research. The standard of care in orthodontics is to have patient images (full face, profile) as well as multiple intraoral images (teeth within jaws) before the start, during and at the end of treatment. These are maintained indefinitely by the orthodontic office.

   The intraoral scans of the study participants will be archived analogous to the other routine patients.

ID: HM20021396 View: SF2 - Sharing Plan

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   - ○ Yes
   - ● **No**

2. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   - ● **No - Will not obtain CoC for this study**
   - ○ Yes - CoC has been obtained or issued automatically
   - ○ Yes - CoC request is pending
   - ○ Yes - Plan to submit request for CoC and will amend study/ICF once status of request is known

3. * **Select the way(s) that <u>individual-level</u> information or biospecimens (including DNA) may be used <u>by the VCU PI or VCU study team for other future research projects</u> (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   Will use directly identifiable information or specimens.

- ☐ *('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page*)
- ☐ Will use de-identified or indirectly identifiable information or specimens.
  ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)
- ☐ Will use anonymized information or specimens.
  ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)
- ☐ Will use aggregate results (summary-level results), not individual-level information or specimens.
  (The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)
- ☐ Will contribute to an existing registry or repository
  (You will be asked more questions about this on a later page.)
- ☑ **Will not use information/specimens for purposes beyond this study.**
- ☐ Not sure and will submit an amendment when known
- ☐ Other use(s) of individual-level information in a way not listed above

4. * **Select the way(s) the VCU PI/study team may share individual-level information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
   See help text for definitions.
   - ☐ Will share directly identifiable information or specimens with other researchers.
     ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. You will be asked more questions about this on a later page.)
   - ☐ Will share de-identified or indirectly identifiable information or specimens with other researchers.
     ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. You will be asked more questions about this on a later page.)
   - ☐ Will share anonymized information or specimens with other researchers.
     ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)
   - ☐ Will only share aggregate results (summary-level results), not individual-level information or specimens.
     (The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)
   - ☐ Will contribute to an existing registry or repository (You will be asked more questions about this on a later page.)
   - ☐ Will submit data to an NIH genomic data repository (You will be asked more questions about this on a later page.)
   - ☑ **Will not share information/specimens with other researchers.**
   - ☐ Not sure and will submit an amendment when known
   - ☐ Other sharing of individual-level information with other researchers

5. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

   - The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
   - If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
   - The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
   - The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- ○ Yes
- ○ No
- ● **N/A - No sharing will occur**

ID: HM20021396 View: SF2 - Pertinent and Incidental Findings

Pertinent and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - ○ Yes
   - ● **No**

ID: HM20021396 View: SF2 - Risk Benefit Complete

Risk Benefit Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Populations with Special Considerations

Populations with Special Considerations

1. * **Check all participant groups that will be either**

   a) Specifically included in this study or

   b) Discernable in the research data/specimens.

   (Selections will branch)
   - ☑ **Children**
   - ☐ Emancipated minors
   - ☐ Wards of the State
   - ☐ Pregnant women or fetuses
   - ☐ Neonates or Post-delivery Materials
   - ☐ Prisoners
   - ☐ Decisionally Impaired Adults

- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [x] **Individuals with limited English proficiency**
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [ ] None of the Above

ID: HM20021396 View: SF2 - Children

Children

1. * **Check all 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. **If multiple categories are selected above, explain which study groups are covered by each selected category (e.g. treatment vs. control groups):**
3. * **Describe how you plan to obtain permission of parents or legal guardians. If you have indicated this study will fall into categories 406 or 407, please describe here how you will obtain permission from both parents.**
   Parents (or legal guardian) always accompany children during doctor's appointments. During the initial orthodontic consultation appointment, if the child satisfies the inclusion/ exclusion criteria, the attending orthodontist/ resident will inform the parent / legal guardian about the study and will seek their participation.
   Parents' consent to orthodontic treatment is a requirement for treating any children (irrespective of whether they are in the study)
4. * **Describe how children will be assented to participate in the study (i.e. what will the study team do during the assent process to ensure the child understands what the research involves).**
   Children need to be between 16 and 17 to be able to participate in this study. The conversation about the study (if the child is deemed eligible) will involve the resident/ attending, parent/ legal guardian and the child. The purpose of the study as well as the details will be explained verbally in a language that a child can understand. Emphasis will be laid on voluntary child participation (child has the right to decline participation even if the parent consents).

ID: HM20021396 View: SF2 - 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
Orthodontic treatment is expensive, time consuming and is associated with patient expectations/ responsibilities that need to be communicated very effectively. Traditionally, the Department of Orthodontics treats a high number of Hispanic patients but out of all of our patients, maybe 2% of the total require a spanish speaking staff member. We have provided the resumes of staff (who would provide translation services at VCU and at Dr. Kravitz offices) attesting their fluency in Spanish. Dr. Gardner's office will not enrol LEP participants due to lack of resources. The SoD do not have MAARTI or blue phones and traditionally rely on staff to do this service for the patients.

We intend to use the short form consent because we do not anticipate recruiting more than 5% of LEP subjects. In the event, we reach 3 LEP participants (4%), we would submit a translated consent document as an amendment for IRB review and approval prior to further enrollment.

2. * **Describe any additional risks or harms to the individual because of their limited English proficiency and how these will be minimized.**
   No other risks or harms will occur to participants with LEP.
3. **If an interpretor or translator will be involved in the study, upload documentation verifying qualifications.**

ID: HM20021396 View: SF2 - Populations with Special Considerations Section Complete

Populations with Special Considerations Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Study Funding

Study Funding

1. * **Have you applied for funding:**
   - ○ Yes
   - ● **No**
2. **Is this study already funded:**
   - ● **Yes**
   - ○ No
3. * **Select all funding sources for this study (pending or awarded):**
   - ☐ Industry
   - ☐ Direct Federal
   - ☐ Indirect Federal
   - ☐ State/Local Government
   - ☐ Non-Profit - Sponsored Project
   - ☐ Non-Profit - Gift
   - ☐ Internal Grant

- [x] **Investigator/Departmental Funds**
- [ ] None
- [ ] Other

4. **Select all related proposals:**

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

There are no items to display

ID: HM20021396 View: SF2 - Types of Sites

Types of Sites

VCU Site Information

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
   - [ ] VCU Monroe Park Campus
   - [ ] VCU Qatar
   - [x] **Other VCU Site**

   Non-VCU Site Information

   Non-VCU sites should be selected whenever any of the following situations apply::
   a) Non-VCU sites that will be collaborating on a VCU-led study
   b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
   c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
   d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * **Select any of the following non-VCU sites utilized in this study:**
   - [ ] McGuire VAMC
   - [ ] Foreign Sites
   - [x] **Other Non-VCU Sites**
   - [ ] No Non-VCU Sites

3. * **Is this a multi-center study being led by VCU?**
   ○ Yes ● **No**

4. * **List all Non-VCU sites and locations:**

   Provide information only for sites that have agreed to participate or given permission for study activities to occur. For Single IRB studies where VCU will be the IRB of record, list all anticipated sites that will rely on VCU IRB, and in their Role indicate that site-specific materials and agreements will be submitted in amendments.

Name	Role	Adequacy	IRB	FWA
Gardner Orthodontics, 1206 Willow Lawn Dr,	Dr. Graham Gardner owns and runs the exclusive orthodontic practice in Richmond. He is also an adjunct faculty in the Department of Orthodontics at VCU SoD. Dr. Gardner will identify potential participants and recruit them in the study if the patient	Dr. Gardner is an expert in Invisalign treatment and is rated as Invisalign	Site Engaged - - Does not regularly	

Richmond, VA 23226	meets the inclusion/ exclusion criteria and sign the informed consent. He will inform the PI once the consent is obtained. The PI will then relay the randomized assignment of the attachment design to Dr. Gardner. The patient will be treated in Dr. Gardner's office and all necessary data (intraoral scans and ClinCheck) will be shared with the PI through a HIPAA-secure portal maintained by Align Technology. All patient information (including demographic information and photos) are maintained in the cloud and can be accessed only by a Invisalign-registered doctor or staff. This access is restricted by an username and password.	VIP Diamond Plus Providers, the highest in terms of experience with Invisalign. He is more than qualified to deal with any unexpected problems that may arise from the treatment.	conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.
Kravitz Orthodontics, 25055 Riding Plaza, Suite 110 South Riding VA 20152	Dr. Kravitz will identify potential participants and recruit them in the study if the patient meets the inclusion/ exclusion criteria and sign the informed consent. He will inform the PI once the consent is obtained. The PI will then relay the randomized assignment of the attachment design to Dr. Kravtiz. The patient will be treated in Dr. Kravitz's office and all necessary data (intraoral scans and ClinCheck) will be shared with the PI through a HIPAA-secure portal maintained by Align Technology. All patient information (including demographic information and photos) are maintained in the cloud and can be accessed only by a Invisalign-registered doctor or staff. This access is restricted by username and password.	Dr. Kravitz is an expert in Invisalign treatment and is rated as Invisalign VIP Diamond Plus Provider, the highest in terms of experience with Invisalign. He is more than qualified to deal with any unexpected problems that may arise from the treatment.	Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. * **How will communication occur between sites for discussion of study conduct, unexpected problems, project modifications, and interim results:**
Consider the following in your response:
- how frequently communication will occur between sites
- how are sites instructed to report unanticipated problems, adverse events, or noncompliance
- how sites can communicate needed revisions to study procedures
- who will dissimenate IRB decisions
- who will notify the IRB of potential problems and changes to the protocol
This study involves Department of Orthodontics and 2 private practices in VA. At all places, the attending orthodontist will identify and manage any unanticipated problems as they would in the case of their regular (non study) patients. Any study specific UP or adverse events and non compliance in the private practices will be conveyed to the PI as they arise

6. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent	Consent form Version 5 clean.pdf	0.14	6/8/2021 6:33 PM	Parthasarathy Madurantakam	Consent/Assent/Information Sheet	Yes
View	Dr. Gardner Independent Investigator Agreement	Dr. Gardner Agreement_fully executed.pdf	0.02	6/4/2021 6:10 PM	Justin Groody	Non-VCU site submission form	Yes
View	Dr. Kravitz Independent Investigator Agreement	Dr. Kravitz Agreement_fully executed.pdf	0.02	6/4/2021 6:09 PM	Justin Groody	Non-VCU site submission form	Yes
View	Interpreter's Resume 3	Dr. Kravitz Resume (Noemi).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes

View	Interpreter's Resume 2	VCU Resume (Carlos).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes
View	Interpreter's Resume 1	VCU Assistant Resume (Andrea).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes
View	Cost coverage form	CAForm1_Lindauer_HM20021396_11May2021.pdf	0.01	5/11/2021 3:45 PM	Parthasarathy Madurantakam	Ancillary Committee Approval	Not Applicable
View	Steven Lindauer Biosketch	Lindauer biosketch.pdf	0.01	4/7/2021 12:12 AM	Justin Groody	CV/Biosketch	Yes
View	Justin Groody Biosketch	BioSketch.docx	0.01	4/7/2021 12:10 AM	Justin Groody	CV/Biosketch	Yes

ID: HM20021396 View: SF2 - Personnel

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:
Conflict of interest investigators, including
The PI
The Lead Student/Trainee Investigator,
Medically/Psychologically responsible investigator(s), and
Other personnel whose riles are essential to the conduct of the research.

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records. PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Steven Lindauer	Principal Investigator		Data Analysis Project Coordination Participant Consent Data Management Data Collection - Clinical Participant Identification Study Design Participant Recruitment Clinical Services		Experience - Research Experience - Clinical		yes
View	Bhavna Shroff	Co/Sub-Investigator		Data Analysis Project Coordination Participant Consent		Experience - Research Experience - Clinical		no

			Data Management Data Collection - Clinical Participant Identification Study Design Participant Recruitment Clinical Services		
View	Parthasarathy Madurantakam	Co/Sub-Investigator	Project Coordination Study Design	Experience - Research	no
View	Caroline Carrico	Statistician	Data Analysis Project Coordination Data Management Study Design Data Coding	Experience - Research	no
View	Justin Groody	Lead Student/Trainee Investigator (leading their own project)	Data Analysis Project Coordination Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment	Trainee	yes
View	Nicholas Lynch	Trainee/Student(working on project)	Participant Consent Data Collection - Clinical Participant Identification Participant Recruitment Clinical Services	Experience - Clinical	no
View	Tonya Spangler	Trainee/Student(working on project)	Participant Consent Data Collection - Clinical Participant Identification Participant Recruitment Clinical Services	Experience - Clinical	no
View	Jordan Lamb	Trainee/Student(working on project)	Participant Consent Data Collection - Clinical	Experience - Clinical	no

Participant Identification

Participant Recruitment

Clinical Services

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Dr. Neal Kravtiz	Co/Sub-Investigator		Participant Consent Data Collection - Clinical Participant Identification Participant Recruitment		Experience - Clinical Education and/or Professional Preparation		no
View	Dr. Graham Gardner	Co/Sub-Investigator		Participant Consent Data Collection - Clinical Participant Identification Participant Recruitment		Experience - Clinical Education and/or Professional Preparation		no

3. **If independent investigators or community engaged investigators are listed above, describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
Both independent investigators will complete the CITI training and submit the documentation of completion to the PI prior to enrolling participants in their offices.

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

ID: HM20021396 View: SF2 - Conflict of Interest

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**

   Financial interests include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project.

   ○ Yes
   ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**

   Non-financial interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,

- serving as an unpaid advisory board member or officer/director with a related entity, and
- equity or business ownership in a company that has yet to make a profit and is related to this project
- conflicts of time/effort,
-personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study

○ Yes
● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.

ID: HM20021396 View: SF2 - Other VCU Requirementsv2

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. **Cost Coverage Analysis**
Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/compliance_program/research_coverage.htm

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
● **Yes**
○ No
○ Not Applicable

2. **ClinicalTrials.gov Program & OnCore**
For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**
● **Yes** ○ No

2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

- Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
- When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
- When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).
● **Yes** ○ No

3. **Community Engagement**
For more information, see https://community.vcu.edu/

1. * **Is there a community partner in this research study?**

○ Yes
● **No**

4. **Family Educational Rights and Privacy Act (FERPA) Requirements**
For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
○ Yes
● **No**

5. **General Data Protection Regulation (GDPR) Requirements**
Contact the VCU Research Data Privacy Office with questions about GDPR requirements: https://research.vcu.edu/data_privacy

1. * **Does this study involve the VCU site, or any sites under the VCU IRB's oversight, obtaining data in, or from, the European Economic Area? (see Help Text for list of countries included in the EEA)**
○ Yes
● **No**

6. **Information Security**
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan.
● **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
○ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool in determining the data classification category selected in Question 1:**
● **Yes**
○ No

.

7. **Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)**
For guidance, see https://www.massey.vcu.edu/research/protocol-review/

1. * **Does this study involve any of the following?**
- Research involving patients with cancer, their families or their health care providers
- Research involving cancer screening, diagnosis or prevention
- Secondary data collected from cancer patients or their medical records
- Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population
○ Yes
● **No**

8. **VCU Health Department of Patient Centered Services**

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**
○ Yes

- (●) **No**
- ( ) Not Applicable

9. **VCU Faculty-Held IND or IDE**
   For guidance, see **http://go.vcu.edu/indide**

10. **VCU Health System locations**

    1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, VCU Medical Center and Massey Cancer Center)?**
       - ( ) Yes
       - (●) **No**

11. **VCUHS Department of Pathology**
    Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

12. **VCU Institutional Biosafety Committee (IBC)**
    To contact the Biosafety Office see their website at: https://research.vcu.edu/ibc

    1. * **Does this project involve the use of Bio-Hazardous Substances such as gene transfer, use of organisms or their products, biological toxins, and/or viruses? See the IBC website for more information about when review is required.**
       - ( ) Yes
       - (●) **No**

    2. * **Does this project involve recombinant DNA (rDNA) and/or synthetic nucleic acids?**
       - ( ) Yes
       - (●) **No**

13. **VCU Radiation Safety Committee (RSC)**
    To contact the Radiation Safety Section see their website at: https://research.vcu.edu/rsc

    1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
       - ( ) Yes
       - (●) **No**

14. **Virginia-Stem Cell Research Oversight (SCRO)**
    For guidance, contact the Office of Research Integrity and Ethics (ORIE) at: ORIE@vcu.edu

    1. * **Does this study involve stem cells?**
       - ( ) Yes
       - (●) **No**

15. **VCU Scientific Review Committee (SRC)**
    For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

    1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**
       - ( ) Yes
       - (●) **No**

16. **Upload any documents requested in the questions above:**

ID: HM20021396 View: SF2 - HIPAA

HIPAA

HIPAA Privacy Board Requirements

For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - [x] **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - [ ] Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)

2. * **Summarize the types of health information that will be obtained or used in this research. Do not describe only the identifiers that you will collect or use during the study.**
   EHR of potential study participants will be accessed to screen for eligibility. Specifically, results of comprehensive oral exam, x-rays/ images, treatment plans and patient visit notes will be accessed.

3. * **Describe the source(s) of the protected health information (e.g. which clinical databases):**
   The electronic health record system used in School of Dentistry (axiUm).

4. * **Does the PI certify that this study's access to and use of the protected health information is limited to the minimum amount necessary to be able to effectively conduct the research?**
   - (●) **Yes** ( ) No

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
   - [ ] 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 (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)**
   - [x] **Signed Authorization Combined with Consent Form**
   - [ ] Signed Authorization as Stand-Alone Form

ID: HM20021396 View: SF2 - 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. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:** ***(Alternative question phrasing: How do the risk(s) of this use of identifiable health information compare to the risks to privacy a person might reasonably experience in normal everyday life?).***
   The partial waiver is intended to screen and identify potential participants. Upon subject identification, full, signed authorization prior to study enrollment.

3. * **If you selected "Identify possible participants to recruit" above, describe when will the 18 HIPAA identifiers be destroyed for those who do not eventually enroll in the study?**
   - [ ] Following Participant Contact
   - [x] **Upon Reaching Study Accrual Objectives**

☐ Other

4. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
   No additional personnel will have access to the PHI

5. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
   (Alternative question phrasing: Why is this partial waiver necessary to make the study achievable or viable?)
   All study participants need to fit specific inclusion/ exclusion criteria as detailed earlier. There is no way to assess patient eligibility without this screening/ consultation appointment. The partial waiver of authorization provides the mechanism to access the PHI which is pivotal for screening and recruiting research study participants

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

   A) 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.

   B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB/Privacy Board.

   C) I will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above.

   D) I assume responsibility for all uses and disclosures of the PHI by members of my study team.

   ◉ **Yes**

   ○ No

ID: HM20021396 View: SF2 - Institutional Requirements Complete

Institutional Requirements Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: HM20021396 View: SF2 - Documents

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
   A list of potential documents is given in the help text.

   NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

   Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
   - Click the Update button located to the left of the document to be updated.
   - In the Add Document window, click the Choose File or Browse button, select the file you are adding, and

click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent	Consent form Version 5 clean.pdf	0.14	6/8/2021 6:33 PM	Parthasarathy Madurantakam	Consent/Assent/Information Sheet	Yes
View	Dr. Gardner Independent Investigator Agreement	Dr. Gardner Agreement_fully executed.pdf	0.02	6/4/2021 6:10 PM	Justin Groody	Non-VCU site submission form	Yes
View	Dr. Kravitz Independent Investigator Agreement	Dr. Kravitz Agreement_fully executed.pdf	0.02	6/4/2021 6:09 PM	Justin Groody	Non-VCU site submission form	Yes
View	Interpreter's Resume 3	Dr. Kravitz Resume (Noemi).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes
View	Interpreter's Resume 2	VCU Resume (Carlos).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes
View	Interpreter's Resume 1	VCU Assistant Resume (Andrea).pdf	0.01	6/3/2021 1:10 PM	Justin Groody	CV/Biosketch	Yes
View	Cost coverage form	CAForm1_Lindauer_HM20021396_11May2021.pdf	0.01	5/11/2021 3:45 PM	Parthasarathy Madurantakam	Ancillary Committee Approval	Not Applicable
View	Steven Lindauer Biosketch	Lindauer biosketch.pdf	0.01	4/7/2021 12:12 AM	Justin Groody	CV/Biosketch	Yes
View	Justin Groody Biosketch	BioSketch.docx	0.01	4/7/2021 12:10 AM	Justin Groody	CV/Biosketch	Yes

ID: HM20021396 View: SF2 - Documents Complete

Documents Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

End of Application

Click Continue below to exit and submit this project

ID: HM20021396 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Consent
2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☑	**Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☑	**Signed Assent by Child or Decisionally Impaired Adult**
☐	Verbal Assent by Child or Decisionally Impaired Adult
☑	**Short Form Consent (limited applicability)**
☐	None of the Above (select waiver below)

3. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☑	**Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)**
☐	Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☑	**Lead Student/Trainee Investigator (leading their own project)**
☐	Research Coordinator
☐	Research Nurse
☐	Consultant
☐	Research Assistant

- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
- [x] **Other**
- [ ] N/A: Requesting Waiver of Consent

5. **If Other is selected, explain:**
   dental assistants who support the clinic operations

6. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
   Consent process will start when treating orthodontists/ residents deem the patient may be eligible based on established inclusion/ exclusion criteria. Any member of the study team will present the research study in detail in a semi private room in the treating orthodontic clinic to potential participants. If the patient agrees to participate in the study, the consent document document will be presented and their signature obtained. If the participant is not an adult, the conversation will include the parent/ legal guardian and their signatures obtained. Children assent will be obtained when appropriate

7. * **Describe the process for minimizing any potential perception of undue influence to participate when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   All potential participants wilfully seek orthodontic care at any of the three study locations. These subjects choose to become patients after the initial consultation appointment. There is no pre-existing relationships between the treating resident / orthodontist and the potential patient. In this sense, study participants are no different from any other patient. In any case, the study team will make it clear to the potential participant that the participation is completely voluntary and non-participation will not affect the intended treatment in any way.

8. * **How much time will participants be given to make a decision:**
   They would be given 2 weeks to make a decision.

9. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
   This is a short term study that will last a maximum of 6 months. In the unlikely situation that the participant enters adulthood at any stage of the study (while actively on the first series of aligners or during data analysis), we will reconsent him/her using the adult consent document.
   Even though the study itself lasts only 6 months, the comprehensive orthodontic treatment would take much longer (12-18 months). In a vast majority of cases, incisor correction is done at the start and we expect all data analysis to be completed within a few months after the second scan. There are 2 possibilities when the issue of reconsenting arise:

   a. If the participants turns 18 while they are still on aligner therapy (irrespective of whether they are on initial series or beyond): In these cases, the study team will have an opportunity to see the participant in person for routine follow-up and will re-consent in person
   b. In the rare instance where the patients are off aligner therapy when data analysis is still in progress, the study team will reach out to the participant over phone and will seek reconsenting. We have checked the box for waiver of documentation of reconsent.

ID: HM20021396 View: SF_IRB_StudyLocation_NonVCUSitesDetails

Non-VCU Site Details

1. * **Name of institution or site:**
   Gardner Orthodontics, 1206 Willow Lawn Dr, Richmond, VA 23226

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing:**
   Dr. Graham Gardner owns and runs the exclusive orthodontic practice in Richmond. He is also an adjunct faculty in the Department of Orthodontics at VCU SoD.

Dr. Gardner will identify potential participants and recruit them in the study if the patient meets the inclusion/ exclusion criteria and sign the informed consent. He will inform the PI once the consent is obtained. The PI will then relay the randomized assignment of the attachment design to Dr. Gardner. The patient will be treated in Dr. Gardner's office and all necessary data (intraoral scans and ClinCheck) will be shared with the PI through a HIPAA-secure portal maintained by Align Technology. All patient information (including demographic information and photos) are maintained in the cloud and can be accessed only by a Invisalign-registered doctor or staff. This access is restricted by an username and password.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
Dr. Gardner is an expert in Invisalign treatment and is rated as Invisalign VIP Diamond Plus Providers, the highest in terms of experience with Invisalign.
He is more than qualified to deal with any unexpected problems that may arise from the treatment.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
- ○ Site Engaged -- Requests to Rely on VCU IRB Review
- ○ Site Not Engaged -- IRB Review Not Required
- ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

ID: HM20021396 View: SF_IRB_StudyLocation_NonVCUSitesDetails

Non-VCU Site Details

1. * **Name of institution or site:**
Kravitz Orthodontics, 25055 Riding Plaza, Suite 110 South Riding VA 20152

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing:**
Dr. Kravitz will identify potential participants and recruit them in the study if the patient meets the inclusion/ exclusion criteria and sign the informed consent. He will inform the PI once the consent is obtained. The PI will then relay the randomized assignment of the attachment design to Dr. Kravtiz. The patient will be treated in Dr. Kravitz's office and all necessary data (intraoral scans and ClinCheck) will be shared with the PI through a HIPAA-secure portal maintained by Align Technology. All patient information (including demographic information and photos) are maintained in the cloud and can be accessed only by a Invisalign-registered doctor or staff. This access is restricted by username and password.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
Dr. Kravitz is an expert in Invisalign treatment and is rated as Invisalign VIP Diamond Plus Provider, the highest in terms of experience with Invisalign. He is more than qualified to deal with any unexpected problems that may arise from the treatment.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
- ○ Site Engaged -- Requests to Rely on VCU IRB Review

- ○ Site Not Engaged -- IRB Review Not Required
- ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Steven Lindauer
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ● **Yes**
   - ○ No
3. * **Roles:**

- ☑ **Principal Investigator**
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☐ Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee

- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Bhavna Shroff
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

- [ ] Other

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Parthasarathy Madurantakam
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ○ Yes
   - ● **No**
3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [x] **Project Coordination**
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Caroline Carrico
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☑ **Statistician**
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☐ Other

4. * **Study related responsibilities:**

Study Design

- [x]
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Justin Groody
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ● **Yes**
   ○ No
3. * **Roles:**

   ☐ Principal Investigator
   ☐ Co/Sub-Investigator
   ☐ Medical or Psychological Responsible Investigator
   ☑ **Lead Student/Trainee Investigator (leading their own project)**
   ☐ Research Coordinator
   ☐ Research Nurse
   ☐ Consultant
   ☐ Research Assistant
   ☐ Pharmacist
   ☐ Statistician
   ☐ Regulatory Coordinator
   ☐ Trainee/Student(working on project)
   ☐ Other
4. * **Study related responsibilities:**

   Study Design

- [x]
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [x] **Trainee**
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Nicholas Lynch
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

   ☐ Principal Investigator
   ☐ Co/Sub-Investigator
   ☐ Medical or Psychological Responsible Investigator
   ☐ Lead Student/Trainee Investigator (leading their own project)
   ☐ Research Coordinator
   ☐ Research Nurse
   ☐ Consultant
   ☐ Research Assistant
   ☐ Pharmacist
   ☐ Statistician
   ☐ Regulatory Coordinator
   ☑ **Trainee/Student(working on project)**
   ☐ Other
4. * **Study related responsibilities:**

   Study Design

- [ ]
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Tonya Spangler
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

   ☐ Principal Investigator
   ☐ Co/Sub-Investigator
   ☐ Medical or Psychological Responsible Investigator
   ☐ Lead Student/Trainee Investigator (leading their own project)
   ☐ Research Coordinator
   ☐ Research Nurse
   ☐ Consultant
   ☐ Research Assistant
   ☐ Pharmacist
   ☐ Statistician
   ☐ Regulatory Coordinator
   ☑ **Trainee/Student(working on project)**
   ☐ Other
4. * **Study related responsibilities:**

   Study Design

- [ ]
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel

Personnel

1. * **Name:**
   Jordan Lamb
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☑ **Trainee/Student(working on project)**
- ☐ Other

4. * **Study related responsibilities:**

- Study Design

- [ ]
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [x] **Clinical Services**
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student

Other

☐

7. **Additional or Emergency Phone:**

ID: HM20021396 View: Personnel_NonVCU

Personnel - Non-VCU

1. * **Name:**
   Dr. Neal Kravtiz
2. * **Name of Non VCU Institution:**
   Kravitz Orthodontics
3. **Affiliation:**
   Independent Investigator / Individual Investigator Agreement needed
4. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   ○ Yes

   ● **No**
5. * **Indicate whose COI policy this individual will follow:**

   Anyone designated as a COI Investigator who will follow VCU's COI Policy must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu). See the help text for additional instructions.
   Individual not a COI Investigator
6. * **Roles:**

- ☐ Principal Investigator
- ☑ **Co/Sub-Investigator**
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)

- [ ] Other

7. **If other role is selected, explain:**
8. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

9. **If other responsibility is selected, explain:**
10. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes
11. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [ ] Experience - Research

Experience - Clinical

- [x]
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

12. **If other qualification is selected, explain:**
13. * **Email:**
    nealkravitz@gmail.com
14. * **Office Phone:**
    703-722-2900
15. **Home Phone:**
16. **Alternate or Emergency Phone:**

ID: HM20021396 View: Personnel_NonVCU

Personnel - Non-VCU

1. * **Name:**
   Dr. Graham Gardner
2. * **Name of Non VCU Institution:**
   Gardner Orthodontics
3. **Affiliation:**
   Independent Investigator / Individual Investigator Agreement needed
4. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.
   - ○ Yes
   - ● **No**
5. * **Indicate whose COI policy this individual will follow:**

   Anyone designated as a COI Investigator who will follow VCU's COI Policy must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu). See the help text for additional instructions.
   Individual not a COI Investigator
6. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator

- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

7. **If other role is selected, explain:**
8. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

9. **If other responsibility is selected, explain:**
10. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
    Yes
11. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

12. **If other qualification is selected, explain:**
13. * **Email:**
    gardnergrins@hotmail.com
14. * **Office Phone:**
    804-263-4716
15. **Home Phone:**
16. **Alternate or Emergency Phone:**

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1. * **Document Name:**
   Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent form Version 5 clean.pdf(0.14)

ID: HM20021396 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Dr. Gardner Independent Investigator Agreement
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   Dr. Gardner Agreement_fully executed.pdf(0.02)

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Add Document

1. * **Document Name:**
   Dr. Kravitz Independent Investigator Agreement
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   Dr. Kravitz Agreement_fully executed.pdf(0.02)

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1. * **Document Name:**
   Interpreter's Resume 3
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Dr. Kravitz Resume (Noemi).pdf(0.01)

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1. * **Document Name:**
   Interpreter's Resume 2
2. * **Type:**
   CV/Biosketch
3. * **File:**
   VCU Resume (Carlos).pdf(0.01)

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1. * **Document Name:**
   Interpreter's Resume 1
2. * **Type:**
   CV/Biosketch
3. * **File:**
   VCU Assistant Resume (Andrea).pdf(0.01)

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1. * **Document Name:**
   Cost coverage form

2. * **Type:**
   Ancillary Committee Approval
3. * **File:**
   CAForm1_Lindauer_HM20021396_11May2021.pdf(0.01)

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1. * **Document Name:**
   Steven Lindauer Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Lindauer biosketch.pdf(0.01)

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Add Document

1. * **Document Name:**
   Justin Groody Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   BioSketch.docx(0.01)