VCU Office of Research and Innovation

Date: Thursday, July 1, 2021 10:30:19 AM Print Close

ID: MS1_HM20021188 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Susie Goolsby
2. * **Study Title:**
   Effects of an external oral irrigation device on patients with dry mouth
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**
4. * **Please select the primary department or center that this study is being conducted under:**
   Dentistry
5. **If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:**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

6. **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	

7. * **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: MS1_HM20021188 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: MS1_HM20021188 View: SF2 - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**
   ● **VCU IRB**
   ○ WCG IRB
   ○ NCI Central IRB
   ○ Advarra IRB
   ○ Other IRB

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

ID: MS1_HM20021188 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. * **Which option(s) best describe the way(s) this study•s procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   ☑ **In-person interactions / interventions with participants**

- ☐ Remote interactions / interventions with participants
- ☐ Secondary data/specimen analyses and no contact with study participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   No, not possible to convert to remote activities
4. * **Does this study involve greater than minimal risk:**
   ○ Yes ● **No**
5. * **Review type requested: (subject to IRB approval):**
   ○ Full Board
   ● **Expedited**
   ○ Exempt

The IRB has determined that the selected types of anticipated individual and social benefit 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. This information may be used by the IRB in triaging studies during an emergency situation.
There are no items to display

The following information applies to studies being reviewed by the VCU IRB.

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 or the study is being reviewed by an external IRB.

6. **For Expedited Studies:**

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 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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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: MS1_HM20021188 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.**

   Dry mouth is a medically based condition that impairs many facets of patients quality of life. Persistent dry mouth, resulting from diminished or low salivary flow, contributes to burning mucosa, dental caries, difficulty with chewing swallowing and digestion of food, and candidiasis overgrowth. Current treatments focus on palliative care to rehydrate the mouth primarily with water using of chipped ice, sipping water throughout the day, and applying moisturizing gels and liquids intraorally through the day. However, the effects of these treatments are temporary at best. There are more invasive and systemic treatments, but their use and effectiveness is limited, and may have unpleasant side effects. Medical devices have been employed to manage various systemic conditions in the last 15 years. Studies have demonstrated that the use of medical devices improve health outcomes due to mitigation of compliance and behavior modification issues, and therefore improvement in the health, and feeling of well beings in patients. The Voutia external oral irrigation device was designed to address the quality of patients lives who suffer from dry mouth. Instead of patients carrying ice chips or water to use throughout the day, the device delivers continuous, hands-free water in adjustable flow levels. Early patient comments suggest an improvement in the quality-of-life issues associated with dry mouth. The aims of this study are to 1) assess patient perception of Oral Health Related Quality of Life (OHRQoL) using the Oral Health Impact Profile (OHIP-14) and the Xerostomia Inventory (XI), 2) assess salivary flow using salivary testing, and 3) mucosal appearances using the Clinical Oral Dryness Score (CODS) before and after the use of the Voutia device to deliver water intraorally for 4-6 weeks.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Medication and systemically-induced oral dryness can result in various conditions resulting in a severe reduction in quality of life. Current treatments given for diminished or no salivary flow are most often palliative and do not offer long term relief.
   This study's hypothesis is based on assessing the effectiveness of treating dry mouth through water rehydration using this extra oral water pump/irrigation device. Will the water pumped into the patient's mouths by means of this continuous, hands-free device effectively relieve the symptoms of oral dryness? Will the use of a water pump/irrigation device, instead of the use of current palliative treatment modalities, positively affect quality of life of patients who experience oral dryness?

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aims of this study were 1) assess patient perception of Oral Health Related Quality of Life (OHRQoL) using the Oral Health Impact Profile (OHIP-14) and the Xerostomia Inventory (XI), 2) assess clinical changes using salivary testing, and 3) mucosal appearances using the Clinical Oral Dryness Score (CODS) during clinical exam.

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

   The Voutia external oral irrigation device was designed to address the quality of patients lives who suffer from dry mouth. The product manufacturer has reported early patient comments suggest an improvement in the quality-of-life issues associated with dry mouth.
   This study is designed to measure this further, and offer statistical analysis to determine if the effects are significant.

5. * **Describe any potential for direct benefits to participants in this study:**
   Relief of the following:
   Need to sip liquids to aid in swallowing food
   Dryness when eating a meal
   Getting up at night to drink
   Difficulty in eating dry foods
   Using sweets or cough lollies to relieve dry mouth
   Extraoral and skin dryness
   Dry eyes, nose, and lips

   Additionally as pertains to quality of life, relief from:
   Trouble pronouncing any words because of problems with your teeth, mouth or dentures.
   Worsened sense of taste.
   Painful aching in the mouth.
   Finding it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures.
   Being self-conscious because of your teeth, mouth or dentures.
   Feeling tense because of problems with your teeth, mouth or dentures.
   Unsatisfactory diet restrictions because of problems with your teeth, disability mouth or dentures.
   Interrupted meals because of problems with your teeth, mouth or dentures.
   Difficulty relaxing because of problems with your teeth, disability mouth or dentures.
   Embarrassment because of problems with your teeth, mouth or dentures.
   Irritability with other people because of problems with disability with your teeth, mouth or dentures.

Difficulty doing your usual jobs because of problems with your teeth, mouth or dentures.
Feeling that life in general was less satisfying because of problems with your teeth, mouth or dentures.
Inability to function because of problems with your teeth, mouth or dentures.

And clinically, alleviation of:

1) mirror sticks to buccal mucosa
2) mirror sticks to tongue
3) frothy saliva
4) no saliva pooling in floor of mouth
5) tongue shows loss of papillae
6) altered/smooth gingival architecture
7) glassy appearance of other oral mucosa, especially palate
8) tongue lobulated/fissured
9) active or recently restored (last 6 months) cervical caries (more than 2 teeth)
10) debris on palate (excluding under dentures)

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
Many different groups of people suffer from chronic dry mouth. This condition can be caused by medications, or health conditions, and can make it difficult to eat speak, and/or remain active. Standard treatment for dry mouth include using medications, rinses, and sipping liquids throughout the day. These treatments help some patients, but many patients still suffer silently with the discomfort of constant oral dryness.
The Voutia irrigation device is a non-surgical, external pump designed to pulse water into the mouth at a rate set by the patient . It is designed to help reduce the need for medications, rinses, and carrying and sipping beverages throughout the day, during meals, during exercise, and during sleeping times.
We want to use our clinical exam and survey to measure the effect of using the Votia device and learn if it will help people suffering from dry mouth to have an improvement in their quality of life, as well as in the health of their mouths.

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

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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.
25

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

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:**
This is a pilot study so the goal is not to power any statistical tests. This sample size is based on the number of available devices and clinic feasibility. This sample size should provide sufficient estimates to calculate the sample size requirements for a larger study if the pilot study justifies.

4. * **List the study inclusion criteria:**
Patients who report a dry mouth (xerostomia) to be screened. The OHIP-14, CODS, and the XI will be completed for those patients, along with stimulated and resting salivary flow testing to determine extent of oral dryness. The patients who report xerostomia (dry mouth) and are diagnosed after testing with hypofunctioning salivary glands will be included.
These patients may experience salivary hypofunction due to any of the following conditions: medication-induced, Sjogren's or other connective tissue disorders, Diabetes Mellitus, smoking-induced, post radiation therapy, or glandular dissection.
The clinics used for patient recruitment during this study treat adults only, and so children will not included.

5. * **List the study exclusion criteria:**
Patient who after testing do not exhibit salivary hypofunction.

The clinics used for patient recruitment during this study treat adults only, and so children will not included.

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.**
   The oral irrigation device may improve quality of life, and measuring that requires the ability to clearly communicate existing conditions and consequent effects of use. Because this involves communication between myself and the patient, and I can not ensure that I will have culturally and language-competent translators on hand as need for initial and post- use appointments, and because this is a new and additional treatment modality that poses no significant risk, English-speaking patients will be selected for this pilot study of the device.

ID: MS1_HM20021188 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
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Click Continue below to go to the next section

ID: MS1_HM20021188 View: SF2 - Study Procedures

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   Medication and systemically-induced oral dryness can result in various conditions resulting in a severe reduction in quality of life. Current treatments given for diminished or no salivary flow are most often palliative and do not offer long term relief.
   This study's hypothesis is based on assessing the effectiveness of treating dry mouth through water rehydration using this extra oral water pump/irrigation device. Will the water pumped into the patient's mouths by means of this continuous, hands-free device effectively relieve the symptoms of oral dryness? Will the use of a water pump/irrigation device, instead of the use of current palliative treatment modalities, positively affect quality of life of patients who experience oral dryness?

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aims of this study were 1) assess patient perception of Oral Health Related Quality of Life (OHRQoL) using the Oral Health Impact Profile (OHIP-14) and the Xerostomia Inventory (XI), 2) assess clinical changes using salivary testing, and 3) mucosal appearances using the Clinical Oral Dryness Score (CODS) during clinical exam.

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)

- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [ ] TelegRAM announcements
- [ ] Website text
- [ ] Study-specific web sites (provide the design and text)
- [ ] Social Media
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] 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. Eligibility screening will occur after the initial medical and dental history taking elicits the need to address the patient's xerostomia (dry mouth). The initial medical and dental history are part of all patient encounters, and stored in Axium. The medical and dental histories are completed at the comprehensive oral evaluation visit and subsequently updated at each recall visit. All patient PPI is protected and kept in Axium.
   2. Patients who are being treated at the VCU School of Dentistry in the pre-doctoral clinics will be recruited to participate based on the their reporting xerostomia, or clinically demonstrating signs of xerostomia. Consent to be taken prior to Redcap survey completion.
   2. PI or student dentists will ask the REdcap survey questions and collect the salivary testing for patients who report a dry mouth (xerostomia) and have consented to participate.

   Saliva testing is done for all patients in our clinic who are suspected to have reduced salivary flow. It is not being done exclusively for this research. It is routinely performed and the instructions for the measuring of salivary flow is attached in documents as "Saliva Testing."

   Flyers will be posted on walls in and around the dental school where our congregate, or wait. Elevators, halls, restrooms, operatories, door of the facility, bulletin boards,.
   (email attached in documents.)
   -When using email, it will be to patients determined by their treating dentist or student doctor to be suffering from dry mouth (xerostomia).
   -Email addresses would be obtained through patient records, in the same manner that their phone numbers are taken from the patient records.
   -As many necessary to obtain the final necessary number of patients for the study; estimate 50.
   -We would send one email, with no follow up.

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
Patients who attend the dental clinic in the school of dentistry have medical and dental histories reviewed. An intraoral clinical exam is also performed to record intramural findings. Upon review by the PI of the recorded medical and dental histories, along with an intramural exam, if a patient has either reported xerostomia, or shows symptoms of salivary hypofunction, the patient will be asked if they would like to participate in the study. If the patient consents, consent will be obtained and the REDCap survey will be completed by the patient.

The patient will be instructed to wear the extra oral irrigation device continuously through the day and night, removing for cleaning and if otherwise necessary, but not for time extending beyond six-eight hours. Use and cleaning instructions to be given according to the manufacturers instructions (see attached Voutia Instruction guide).

After 4-6 weeks, the patient will be instructed to return to the dental school clinic for reexamination and completion of the survey.

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.).
   The wearing of the oral irrigation device and the completion of the survey are done exclusively for research purposes.

   Standard dental exams will be completed for non-research purposes but data from these exam/interviews will be used for the study.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
   Patients are routinely given, and will be given standard instructions for dry mouth if they choose to not participate. These instructions include sipping water through the day, using salivary substitutes through the day, rinsing through the day with baking soda and water rinse, chewing or sucking on sugar-free gums and mints (in particular products containing Xylitol), and the use of 5000 ppm prescription strength fluoride preparations at home in place of OTC toothpaste.

   The device will not be made available to patients who do not choose to participate in the study.

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: MS1_HM20021188 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
   - [x] **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):**
   - [x] **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
   - [ ] Audio / Video recording or photographing participants
   - [x] **Observations**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior)
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **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)**
   - [x] **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: MS1_HM20021188 View: SF2 - Bio-Medical Device Details

Bio-Medical Device Details

1. * **Select the type of device :**
   - [x] **Marketed Device (including 510k device) used as indicated**
   - [ ] Marketed but new indication or intended use
   - [ ] Mobile application with regulatory discretion
   - [ ] Mobile application without regulatory discretion
   - [ ] Investigational device
   - [ ] Humanitarian Use Device (HUD)

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

Device	Manufacturer	Device Risk	IDE	IDE Holder
Voutia	Xeros Dry Mouth Pump Lorin Technologies	Not Designated / Not Required	K173808	Not Required

3. * **Describe how the device will be stored and controlled.**
The patient will be instructed to wear the device continuously, and remove only as needed for cleaning or other needs, not to exceed 6-8 hours.

POWERING ON THE VOUTIA® USING ITS INTERNAL BATTERY
Locate the center button with the round circle.
1. Press and hold the center button for 2-3 seconds.

2. The unit will power on, go through a system check and show the display.
3. If a mode is not selected, the device will enter a sleep mode after 30 seconds.
4. If a flow rate was selected at an earlier use, the system will begin pumping at that setting immediately.
5. If you do not wish the unit to pump, press the "down" arrow until the number "0" is displayed.

POWERING AND CHARGING THE VOUTIA® SYSTEM FROM EXTERNAL POWER
1. Check to make sure the Voutia® Device is not powered on.
2. Plug in the included wall adapter to a standard home wall outlet (110 volt).
3. Plug in the other end of the power adapter to the power jack on the outside of the Voutia® Device.
(Do not force the plugs together; slowly rotate the plug as you apply light pressure.
There is only 1 (one) correct position and they will slide together when aligned.)
4. The Voutia® unit will power on when attached to the wall charger.
5. The unit will go through a system check and show "STANDBY" on the display.

NOTE: If you turn off your Voutia® while charging, you must disconnect the
charger from the unit in order to turn the unit back on.
While connected to an outlet, the Voutia® System will operate normally and charge
the internal Lithium Polymer battery at the same time. You should not need to go without
the system while charging.

TURNING THE POWER OFF
To shut off your Voutia® System, simply locate the center key with the circle on it.
Press and hold down the center key marked "0" for 4- 5 seconds. The device should power off.

NAVIGATING THE DISPLAY
Use the left and right arrow keys to move between the preprogrammed modes
(shown at the top of the LCD display) depending on your activity and needs.
SLP = Sleep mode, (0.1 to 0.3 ml/min recommended, DO NOT EXCEED)
SIT = Resting mode, (0.5 ml/min recommended)
DAY = Daytime mode, (0.4 to 0.7 ml/min recommended)
EXE =Exercise mode, 0.7 to 0.9 ml/min recommended)
PLEASE NOTE: EACH PERSON IS UNIQUE AND THE SELECTION RECOMMENDATIONS
ARE ONLY GUIDELINES. SELECT THE RATE THAT PROVIDES THE BEST RELIEF,
HOWEVER, DO NOT EXCEED THE RECOMMENDED RATE WHEN SLEEPING.
A full description of what mode you have selected will appear in the lower left of the LCD display.
A battery monitor bar is located in the lower right corner of the display so you will know the
Voutia® battery charge status. Selectable modes are: Sleep, Sitting, Daytime, and Exercise.
Once started, your Voutia® System will begin to pump at the selected rate and save this setting for future use.
Make sure you are wearing the accompanying headpiece or fluid spilling will occur.

The device, Headpiece and Tubing should not be stored unless these steps are performed. Storage should be in a cool dry place.
1. Pour out all contents of the bottle.
2. Attach the headpiece to the pump and perform the cleaning procedure described above.
3. After the bottle is emptied, run the device AT ITS MAXIMUM SETTING OF 9 with the headset attached
for 10 minutes to clear any liquid out of the tubes.
4. Detach the reservoir and headset from the main pumping unit.
5. Attach the included 3cc syringe to the outlet port using the included adapter and gently pull the
plunger up to draw any residual fluid from the pumping system that may remain.
6. Attach the 3cc syringe to the Luer connector on the headset and gently draw back on the plunger
to remove any residual fluid in the headset.
7. Disconnect all power sources and store the unit in a cool dry place.

NOTE: Prior to using the unit at a later date, perform the complete cleaning procedure listed above.
The unit should then be ready to use again.

4. A. For each device listed above, **upload documentation of the approved use(s) (operation manual, instructions for use, etc.) or a detailed description of the design, use, and risks of the device.**

B1. If 'Investigational Medical Device' or 'New Use for Marketed Medical Device' was selected above AND the device qualifies for <u>IDE exemption</u> under under 21 CFR 812.2(c), upload one of the following documents for each applicable device:
- A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c).
- External sponsor's protocol including IDE exemption information
- Communication from the external sponsor verifying the IDE exemption
- Communication from the FDA with verification of IDE exemption

B2. Upload at least one of the following documents for <u>each Significant Risk medical device:</u>
- External sponsor's protocol including IDE number
- Communication from the external sponsor verifying the IDE number
- VCU sponsor-investigator's FDA IDE protocol including IDE number
- Communication from the FDA with verification of the IDE number

B3. Upload at least one of the following documents for <u>each Non-Significant Risk medical device:</u>
- External sponsor's protocol including a justification regarding the risk of the device (significant vs. non-

significant)
- Communication from the sponsor holding the IDE, which provides a justification regarding the risk of the device (significant vs. non-significant) according to 21 CFR 812.3(m).

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent	Biomedical_Consent_Template_09282020_Voutia_version 6.0 IRB redline version CT gov_SG.pdf	0.18	7/1/2021 10:30 AM	Susie Goolsby	Consent/Assent/Information Sheet	Yes
View	Study Advertisement	Voutia Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Recruitment Email	Voutia Email Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Saliva Testing	Salivary Testing with stimulated and 3 methods for unstimulated flow testing.pdf	0.01	4/2/2021 8:51 AM	Susie Goolsby	Other	No
View	References	References.docx	0.01	1/5/2021 5:03 PM	Susie Goolsby	Other	Not Applicable
View	Notification of new device	Notification of New Device Establishment Registration.docx	0.01	1/5/2021 12:03 PM	Susie Goolsby	FDA Regulatory Document	Not Applicable
View	510K Summary for Voutia	K173808.510kSummary.Final_Sent001.pdf	0.01	1/5/2021 12:01 PM	Susie Goolsby	Drug/Device Brochure	Not Applicable
View	CV Goolsby	CURRICULUM VITAE _Assoc Prof 2021.docx	0.01	1/5/2021 9:36 AM	Susie Goolsby	CV/Biosketch	Yes
View	Biosketch S Goolsby	Biosketch SGoolsby 2021.docx	0.01	1/4/2021 2:56 PM	Susie Goolsby	CV/Biosketch	Yes
View	Redcap questionnaire for patients	Form1_DryMouthDeviceStudyVouti (1).pdf	0.01	1/4/2021 2:34 PM	Susie Goolsby	Other	Yes
View	Voutia Instruction Guide	user instructions update combined10_12_2020.pdf	0.01	12/15/2020 4:31 PM	Susie Goolsby	Drug/Device Brochure	Yes

ID: MS1_HM20021188 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.
   Secondary data will be recorded from the medical and dental history records in Axium.

   Axium contains all elements of patient EHR, including:
   Health history form which list medical history including comorbidities and medications lists.
   Dental History form which lists patient's dental, demographic, habit, and oral perceptions (pain, appearance, salivary flow, ability to chew diverse foods).
   Clinical examination forms which contain information derived during clinical exam of head and neck anatomy, oral conditions of hard and soft tissues, TMJ conditions and occlusion, risk of caries infections, management of caries infection, and radiographic evaluation of oral, and head and neck hard and soft tissues.

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.**
   N/A

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: MS1_HM20021188 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: MS1_HM20021188 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**

   No compensation to patient
2. **If compensation will be pro-rated, explain the payment schedule.**
3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - ○ Yes
   - ● **No**

ID: MS1_HM20021188 View: SF2 - Contingency Plan

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

ID: MS1_HM20021188 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: MS1_HM20021188 View: SF2 - Consent Process

Consent Process

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

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Voutia Consent	Signed Consent by Participant	No Waivers Requested	Principal Investigator Trainee/Student(working on project)		Not using electronic signature platforms	At time of clinical and survey determination of inclusion. For ongoing purposes, the patient will be informed to contact either the PI or the care provider through email, phone or text, or during other non-study related treatment in the clinical setting, to inform of their desire to return the device and discontinue participation in the study.	Patients will be allowed to end participation at any time. Patients who do onot consent to participation will receive instructions for howmcare that are standard for patients with xerostomia.	Patient is seated upright in the treatment chair and at eye level with PI who will give a brief description of the study. The care provider for the patient will be in the cubicle with the PI and patient at all times. After explanation of the study, the care provider will then finish the consent process in the absence of the PI. Patient may also take a copy of consent and decide after days of consideration, or until	Not applicable; no children will be recruited to participate.

participant capacity is met.

2. **Upload any consent / assent documents:**

ID: MS1_HM20021188 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: MS1_HM20021188 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.

   Device may become damaged, risking battery burns if left near exposed skin. Settings may fail resulting in too much or too little water irrigation.

   Patients may be self conscious concerning wearing the tubing when others may see it.

   Patients may fear being identified for health-related oral dryness, resulting in psychological discomfort.

   Length of pilot study may be too long or too short to gain insightful data.

   There is a risk of a loss of confidentiality, which frequently occurs in studies in which patients with specific health conditions are recruited and followed.

   The oral irrigation device involves risks that are currently unknown or unforeseeable.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   Instructions to be given orally and in written print out format.

   Study may have to be repeated or an addendum requesting extending the study if deemed necessary.

Study activities (recruiting and survey completion) will occur in private dental treatment areas to protect subject privacy.

Patients and their electronic health records assigned to the School of Dentistry are protected under HIPPA.

Patient is allowed to discontinue the study at any time for any reason, and may discontinue use of device during the study for up to 6-8 hours periods of time if necessary.

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):**
   No risk to the community.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   Patients may discontinue participation at any time for any reason.
   If battery burn occurs, discontinue use, seek medical attention to site of burn, and inform investigators immediately.
   Water flow settings can be adjusted. If too much or too little water is flowing through tubing, contact investigators immediately for instructions for adjustment or discontinue use and return to clinical setting for water flow to be adjusted by investigator.

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.:**
   If patient is not willing or capable of following protocol and instructions, and demonstrates behavior that may result in harm due to misuse of the device, that patient will be withdrawn.

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:**
   Any unforeseeable issues with the safe and proper operation of the device would trigger the discontinue of or change in the study protocol.

   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: MS1_HM20021188 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.**
   - [ ] Asking the participant if they are comfortable answering questions in that location
   - [ ] 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.)
   - [x] **Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.**
   - [x] **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
- [ ] 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)
   - [x] **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.**
   Not applicable

ID: MS1_HM20021188 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:**
   - [x] **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
   - [x] **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
   - [x] **N/A no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***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)
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) 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
   - [x] **De-identifying the research data by replacing subjects names with assigned subject IDs**
   - [x] **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**
   - [x] **Only using VCU/VCU Health email addresses for study-related communications**
   - [x] **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
   - [ ] 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.**
   Not applicable

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).**
   Not applicable

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)
   - [ ] Phone Numbers
   - [ ] Facsimile Numbers
   - [ ] E-mail Addresses
   - [x] **Medical Record Numbers**
   - [x] **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.
A study code will be created to ensure the ability to link the study data from the two survey timepoints and to track the devices assigned to the patients and ensure they are returned. Subjects will be assigned a sequential identifier (Subject 1 through Subject 25). The study key will contain the subject's dental record number, contact information, and unique identifier. This is necessary as it will allow for the PI to contact any subjects who do not return with the device and to link subject data from subsequent visits. The study data (survey responses, salivary flow rate data) will be de-identified. No attempts will be made to re-identify the study data.
- The key is stored in password protected excel file on the VCU faculty Google drive folder.
-Access only available to PI and statistician
-The key will be destroyed at the end of the study once the minimum time requirements have been met.

ID: MS1_HM20021188 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
   - [x] **Other**
   - [ ] N/A - study does not require screening procedures
2. **If Other, explain how the information will be handled.**
   Pre-screening and screening data is part of standard care and will be stored in the patient's chart regardless of their eligibility for the study.
3. * **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**
4. * **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

ID: MS1_HM20021188 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. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ○ Yes ● **No**

3. * **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

4. * **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.

- [x] **Not sure and will submit an amendment when known**
- [ ] Other use(s) of individual-level information in a way not listed above

5. * **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.
   - [x] **Not sure and will submit an amendment when known**
   - [ ] Other sharing of individual-level information with other researchers

6. * **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: MS1_HM20021188 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: MS1_HM20021188 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: MS1_HM20021188 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
   - [ ] 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
   - [x] **None of the Above**

ID: MS1_HM20021188 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: MS1_HM20021188 View: SF2 - Study Funding

Study Funding

1. * **Have you applied for funding:**
   - ○ Yes
   - ● **No**
2. **Is this study already funded:**
   - ○ Yes
   - ● **No**

ID: MS1_HM20021188 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 Health Tappahannock Hospital
   - ☐ VCU Medical Center
   - ☐ Other VCU Health Location
   - ☐ VCU Monroe Park Campus
   - ☐ VCU Qatar
   - ☑ **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

☐ Other Non-VCU Sites

☑ **No Non-VCU Sites**

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

4. **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	Biomedical_Consent_Template_09282020_Voutia_version 6.0 IRB redline version CT gov_SG.pdf	0.18	7/1/2021 10:30 AM	Susie Goolsby	Consent/Assent/Information Sheet	Yes
View	Study Advertisement	Voutia Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Recruitment Email	Voutia Email Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Saliva Testing	Salivary Testing with stimulated and 3 methods for unstimulated flow testing.pdf	0.01	4/2/2021 8:51 AM	Susie Goolsby	Other	No
View	References	References.docx	0.01	1/5/2021 5:03 PM	Susie Goolsby	Other	Not Applicable
View	Notification of new device	Notification of New Device Establishment Registration.docx	0.01	1/5/2021 12:03 PM	Susie Goolsby	FDA Regulatory Document	Not Applicable
View	510K Summary for Voutia	K173808.510kSummary.Final_Sent001.pdf	0.01	1/5/2021 12:01 PM	Susie Goolsby	Drug/Device Brochure	Not Applicable
View	CV Goolsby	CURRICULUM VITAE _Assoc Prof 2021.docx	0.01	1/5/2021 9:36 AM	Susie Goolsby	CV/Biosketch	Yes
View	Biosketch S Goolsby	Biosketch SGoolsby 2021.docx	0.01	1/4/2021 2:56 PM	Susie Goolsby	CV/Biosketch	Yes
View	Redcap questionnaire for patients	Form1_DryMouthDeviceStudyVouti (1).pdf	0.01	1/4/2021 2:34 PM	Susie Goolsby	Other	Yes
View	Voutia Instruction Guide	user instructions update combined10_12_2020.pdf	0.01	12/15/2020 4:31 PM	Susie Goolsby	Drug/Device Brochure	Yes

ID: MS1_HM20021188 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	Caroline Carrico	Statistician		Data Analysis Data Management Study Design Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		no
View	Michael Barrett	Trainee/Student(working on project)		Participant Consent Other Data Collection - Clinical Data Entry Data Collection - Interviews/Surveys	Literature review, bibliography, conducting surveys,obtaining consent, research assistance.	Student		yes
View	Susie Goolsby	Principal Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Regulatory Management Data Collection - Clinical Study Design Participant Recruitment Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Ali Alhaddad	Trainee/Student(working on project)		Participant Consent Other Data Collection - Clinical Data Entry Data Collection - Interviews/Surveys	Literature review, bibliography, conducting surveys,obtaining consent, research assistance.	Student		yes

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

There are no items to display

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:

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: MS1_HM20021188 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 interest 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 proje*ct**
   ○ 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
   - conflict 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 If Yes, provide:**
   - Name(s) of the engaged individual(s) with a related non-financial interest
   - Brief description of the non-financial interest
   Any individual named here should also complete a Financial Interest Report (FIR) in the Activity and Interest Report System (AIRS), even if they were not initially designated as a 'COI Investigator.' Ensure that all designated 'COI investigators,' including the PI, and any others listed here with related interests are up to date in the AIRS (https://airs.research.vcu.edu)
   Student Michael Barrett has shadowed and is familiar with the devices' creators. He has no financial interests. He introduced the PI to the creator of the devices, but is currently a full time student at the school.

   The PI (Susie Goolsby) teaches a Cariology course in the dental school, and teaches about the effects of dry mouth in relation to dental cavities and changes to oral mucosa. She is very familiar with the topic, but otherwise has no additional financial or non financial interests.

4. **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.
   None to report.

ID: MS1_HM20021188 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/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

   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 this a community engaged research study? (See help text for definitions)**
      ○ 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. **Research Data Privacy Requirements**
   Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

   1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB's oversight, obtaining data in, or from, a foreign country?**
      ○ Yes ● **No**

   2. **If yes, list the country/countries:**

   3. * **Does this study involve the VCU site (regardless of the IRB of record), 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 at https://go.vcu.edu/dataclassification in determining the data classification category selected in Question 1:**

      - (●) **Yes**
      - ( ) No

   3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be created. See https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/**

      (●) **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 ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see** https://onetrac.vcu.edu/

   1. * **Does this study involve research with any of the following?**

      - VCU Health System patients

      - VCU Health System facilities

      - VCU Health System data

      - ( ) Yes
      - (●) **No**

      If Yes, upload documentation of approval or review by the PROC in this study's topic area.

9. **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

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

11. **VCU Health System locations**

    1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR,**

Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?

- (●) **Yes**
- ( ) No

2. * **The PI has reviewed and agreed to comply with the VCU Health System Research in Patient Care Areas policy (https://research.vcu.edu/compliance_program/vcuhs_policies.htm):**
   - (●) **Yes**
   - ( ) No

12. VCUHS Department of Pathology

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

1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
   - Storage of Microbiology isolates
   - New instrumentation provided by clinical trial/study sponsor, or
   - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)
   - ( ) Yes
   - ( ) No
   - (●) **N/A - my study does not involve any of the listed processes.**

2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**
   - ( ) Yes
   - ( ) No
   - (●) **N/A - my study won't involve specimen retrieval from Pathology**

13. VCU Institutional Biosafety Committee (IBC)

To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following biohazardous agents?**
   - Integrating viruses (viruses that may integrate into the patients' genome)
   - Nonintegrating viruses (viruses that express proteins within patients' cells)
   - Expression or administration of biological toxins
   - Biological agents (bacteria, fungi, viruses, etc.)
   - Introduction or expression of rDNA or synthetic nucleic acids
   - Use of a product (e.g., monoclonal antibodies) produced from virally infected mammalian cells
   - ( ) Yes (●) **No**

14. VCU Radiation Safety Committee (RSC)

To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
   - ( ) 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: MS1_HM20021188 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.**
    - ☑ **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)**
    - ☐ PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entity's 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.**
Patients medical and dental history, salivary flow rates, and surveys that measure oral dryness and effects on quality of life due to oral dryness will be obtained at the start and end of the study.
3. * **Describe the source(s) of the protected health information (e.g. which clinical databases):**
The dental school stores the medical and dental history electronically in Axium; this is where the information will be obtained, in addition to reviews of this information completed at time of appointments.
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
    - ☑ **Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)**
    - ☑ **Signed Authorization Combined with Consent Form**
    - ☐ Signed Authorization as Stand-Alone Form

ID: MS1_HM20021188 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 use of patient PHI for screening is temporary and accessed through our informatics system, and full authorization will be sought from participants who consent, so the use of patient PHI for screening presents no more than minimal risk to participants.
   Screening information will be obtain through our informatics system/department. The risks are mitigated through the use of identifiers and contact information that is either password or VPN protected by the university.

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
   - [ ] Upon Reaching Study Accrual Objectives
   - [x] **Other**

4. * **Since Other was selected above, describe when identifiers will be destroyed for those who do not eventually enroll in the study.**
   The patient dental records contain the identifiers. The identifiers used in the study will be destroyed at the end of the study.

5. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
   The student doctor, or doctors, who treat the patient in our clinic.

6. * **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?)***
   The use of identifiers will allow us to narrow the patients contacted for the study, in effort to find patients who would qualify. This eliminates the need for screening a potentially larger population of patients clinically, while allowing for more patients who qualify to be added to the study over a shorter time span.

7. * **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: MS1_HM20021188 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: MS1_HM20021188 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	Biomedical_Consent_Template_09282020_Voutia_version 6.0 IRB redline version CT gov_SG.pdf	0.18	7/1/2021 10:30 AM	Susie Goolsby	Consent/Assent/Information Sheet	Yes
View	Study Advertisement	Voutia Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Recruitment Email	Voutia Email Advertisement_final Clean.docx	0.06	6/21/2021 10:56 AM	Susie Goolsby	Recruitment/Advertising	Yes
View	Saliva Testing	Salivary Testing with stimulated and 3 methods for unstimulated flow testing.pdf	0.01	4/2/2021 8:51 AM	Susie Goolsby	Other	No
View	References	References.docx	0.01	1/5/2021 5:03 PM	Susie Goolsby	Other	Not Applicable
View	Notification of new device	Notification of New Device Establishment Registration.docx	0.01	1/5/2021 12:03 PM	Susie Goolsby	FDA Regulatory Document	Not Applicable
View	510K Summary for Voutia	K173808.510kSummary.Final_Sent001.pdf	0.01	1/5/2021 12:01 PM	Susie Goolsby	Drug/Device Brochure	Not Applicable
View	CV Goolsby	CURRICULUM VITAE _Assoc Prof 2021.docx	0.01	1/5/2021 9:36 AM	Susie Goolsby	CV/Biosketch	Yes
View	Biosketch S Goolsby	Biosketch SGoolsby 2021.docx	0.01	1/4/2021 2:56 PM	Susie Goolsby	CV/Biosketch	Yes
View	Redcap questionnaire for patients	Form1_DryMouthDeviceStudyVouti (1).pdf	0.01	1/4/2021 2:34 PM	Susie Goolsby	Other	Yes
View	Voutia Instruction Guide	user instructions update combined10_12_2020.pdf	0.01	12/15/2020 4:31 PM	Susie Goolsby	Drug/Device Brochure	Yes

ID: MS1_HM20021188 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: MS1_HM20021188 View: Copy of Bio-Med Devices

Bio-Medical Devices

1. * **Name:**
   Voutia
2. * **Manufacturer:**
   Xeros Dry Mouth Pump Lorin Technologies
3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Not Designated / Not Required
4. * **Indicate the device's IDE number if a protocol was submitted to the FDA for any investigational device or new use of a marketed device (regardless of what the FDA's determination was).**

   Or, if a protocol was not submitted to the FDA:
   - Enter "Abbreviated IDE" if the sponsor or sponsor-investigator has designated the device as a Non-Significant Risk device
   - Enter "IDE Exempt" if the sponsor or sponsor-investigator has determined that the device qualifies for IDE exemption
   - Enter "Regulatory Discretion" for a mobile application with regulatory discretion
   - Enter the FDA-provided HDE number if a HUD is being used in a clinical investigation for the HDE-approved indication(s).

   K173808
5. * **Select who holds the Investigational Device Exemption (FDA-granted IDE or Abbreviated IDE) for the device:**

   ○ External to VCU Sponsor or Investigator

   ○ VCU Sponsor-Investigator

   ○ VCU Sponsor who is not the Investigator

   ● **Not Required**
6. **If someone other than the PI is the sponsor for the IDE, name the entity or individual who will be the IDE sponsor.**
   Jeffrey Ward Cash, DDS

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Biomedical_Consent_Template_09282020_Voutia_version 6.0 IRB redline version CT gov_SG.pdf(0.18)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Study Advertisement
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Voutia Advertisement_final Clean.docx(0.06)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Recruitment Email
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Voutia Email Advertisement_final Clean.docx(0.06)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Saliva Testing
2. * **Type:**
   Other
3. * **File:**
   Salivary Testing with stimulated and 3 methods for unstimulated flow testing.pdf(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   References
2. * **Type:**
   Other
3. * **File:**

References.docx(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Notification of new device
2. * **Type:**
   FDA Regulatory Document
3. * **File:**
   Notification of New Device Establishment Registration.docx(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   510K Summary for Voutia
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   K173808.510kSummary.Final_Sent001.pdf(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   CV Goolsby
2. * **Type:**
   CV/Biosketch
3. * **File:**
   CURRICULUM VITAE _Assoc Prof 2021.docx(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Biosketch S Goolsby
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Biosketch SGoolsby 2021.docx(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Redcap questionnaire for patients

2. * **Type:**
   Other
3. * **File:**
   Form1_DryMouthDeviceStudyVouti (1).pdf(0.01)

ID: MS1_HM20021188 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Voutia Instruction Guide
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   user instructions update combined10_12_2020.pdf(0.01)

ID: MS1_HM20021188 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Voutia 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 all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ Other electronic signature platform
4. **If Other is selected, explain:**
5. * **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)

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

- [x] **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)**
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **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:**
   At time of clinical and survey determination of inclusion.
   For ongoing purposes, the patient will be informed to contact either the PI or the care provider through email, phone or text, or during other non-study related treatment in the clinical setting, to inform of their desire to return the device and discontinue participation in the study.

8. * **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.):**
   Patients will be allowed to end participation at any time. Patients who do onot consent to participation will receive instructions for howmcare that are standard for patients with xerostomia.

9. * **How much time will participants be given to make a decision:**
   Patient is seated upright in the treatment chair and at eye level with PI who will give a brief description of the study. The care provider for the patient will be in the cubicle with the PI and patient at all times. After explanation of the study, the care provider will then finish the consent process in the absence of the PI.

   Patient may also take a copy of consent and decide after days of consideration, or until participant capacity is met.

10. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who**

are no longer decisionally impaired:
Not applicable; no children will be recruited to participate.

ID: MS1_HM20021188 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**
- ☐ Data Collection - Lab

- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] 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)**

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

7. **Additional or Emergency Phone:**

ID: MS1_HM20021188 View: Personnel

Personnel

1. * **Name:**
   Michael Barrett

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
   - [x] **Trainee/Student(working on project)**
   - [ ] Other

4. * **Study related responsibilities:**

   - [ ] Study Design
   - [ ] Data Collection - Lab
   - [x] **Data Collection - Clinical**
   - **Data Collection - Interviews/Surveys**

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

5. * **If other responsibility is selected, explain:**
   Literature review, bibliography, conducting surveys,obtaining consent, research assistance.
6. * **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
7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

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

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Susie Goolsby
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:**

   - [x] **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**
   - [x] **Data Collection - Interviews/Surveys**

- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [x] **Project Coordination**
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **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)**

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

7. **Additional or Emergency Phone:**
   804-828-2977

ID: MS1_HM20021188 View: Personnel

Personnel

1. * **Name:**
   Ali Alhaddad

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
   - [x] **Trainee/Student(working on project)**
   - [ ] Other

4. * **Study related responsibilities:**

   - [ ] Study Design
   - [ ] Data Collection - Lab
   - [x] **Data Collection - Clinical**
   - [x] **Data Collection - Interviews/Surveys**
   - [ ] Data Collection - Direct Observation
   - [ ] Clinical Services

- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [x] **Participant Consent**
- [ ] Regulatory Management
- [x] **Other**

5. * **If other responsibility is selected, explain:**

   Literature review, bibliography, conducting surveys,obtaining consent, research assistance.

6. * **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

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

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

8. **Additional or Emergency Phone:**