VCU Office of Research and Innovation

Date: Thursday, November 4, 2021 12:56:19 PM Print Close

ID: HM20022338 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Vishal Yajnik
2. * **Study Title:**
   Use of Stable Airway Management Device in Monitored Anesthesia Care
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:**
   Anesthesiology
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 **If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:**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
Cohen	David	djcohen@vcu.edu		
Yajnik	Vishal	yajnikv@vcu.edu		

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: HM20022338 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. * **Indicate the FDA regulated product(s) this study involves:**
   - ☐ Drug
   - ☑ **Medical Device**
   - ☐ Biologic
   - ☐ Dietary Supplement
   - ☐ Food/Food Additive
   - ☐ Color Additive
   - ☐ Electronic Products for Human Use (radiation producing)
   - ☐ Other

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

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

ID: HM20022338 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: HM20022338 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.**
   - [x] **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.

Possible or minimal direct benefit to individual participants

ID: HM20022338 View: SF2 - Initial Setup Complete

Initial Setup Complete

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

Click Continue below to go to the next section

ID: HM20022338 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.**

   Anesthesiology has been at the forefront of patient safety in the perioperative setting for many years, including the introduction of innovations in patient monitoring and airway management. The risk involved in anesthesiology remains significant, and multifold, with adverse outcomes ranging from death, to nerve injury, airway complications, and emotional distress. In fact, in the Anesthesia Closed Claims database, from 2005 to 2014, reflected that for the 1,567 claims pertaining to adverse events resulting in patient injury, death accounted for 30%, nerve damage 21%, brain injury 9%, and airway injury 7%. Furthermore, the most common damaging events in perioperative anesthesia care were respiratory (22%) and equipment (20%) events.

   The Anesthesia Closed Claims database project further examined the rapidly expanding role of non-operating room anesthesia (NORA). These scenarios represent a burgeoning expansion of anesthesia care, where anesthesia providers are asked to provide primarily sedation in a range of areas, including gastroenterology endoscopy suites, radiology care suites, and many other locations. The pattern of injury in NORA claims was similar in distribution to claims arising in the OR; however, death and permanent brain damage made up a greater percentage (68%) of NORA claims than OR claims (39%). Most of the claims were related to oversedation with respiratory depression, and one third of the cases were judged to have likely been preventable with better respiratory monitoring. This applied particularly to continuous end-tidal CO2 monitoring, which was used in only 15% of the claims associated with oversedation.

The prevention of injuries ultimately demands situational awareness from individual practitioners and cognitive, nontechnical, and technical skills to address a potentially dangerous clinical scenario before an injury occurs. This has proven challenging given the number of distractions that may be present in the operating room. Maintaining a stable airway in a sedated patient undergoing monitored anesthesia care (MAC) is a critically important aspect of providing a safe anesthetic. Failure to maintain a patent airway and avoid its obstruction results in impaired ventilation. Without correction, this leads to oxygen desaturation, hypoxemia, resulting in potentially devastating cardiac arrest, that may lead to death or anoxic brain injury.

Monitoring arterial oxygen saturation is typically done with peripheral pulse oximetry (SpO2), a non-invasive method of measuring oxygen saturation in red blood cells in the arterial circulation. This is considered a standard monitor by the American Society of Anesthesiologists and usually takes the form of sticker that is placed on a finger, ear lobe, nostril, or forehead during anesthetics and throughout the hospital setting. This is helpful in determining if oxygen desaturation is occurring during anesthesia and sedation, perioperatively. Airway obstruction due to the anesthesia-induced suppression of upper airway reflexes is not uncommon during MAC. The upper airway reflexes consist of many different types of reflex responses such as sneezing, apnea, swallowing, laryngeal closure, coughing, expiration reflex, and negative pressure reflex. Although the activation of upper airway reflexes does not necessarily occur at one particular site of the respiratory tract, individual reflex response is usually considered to be highly specific for the particular respiratory site which has been affected. The upper airway reflexes are modified by many factors such as sleep, anesthesia, and background chemical ventilatory drive. Both depression and exaggeration of upper airway reflexes cause clinical problems. Depression of upper airway reflexes enhances the chance of pulmonary aspiration and compromises the maintenance of the airway, whereas exaggeration of airway reflexes such as laryngospasm and prolonged paroxysm of cough can be harmful and dangerous .
End-tidal CO2 (ETCO2) has been used in multiple studies as a monitor of respiratory suppression. MAC is usually done with multiple bolus doses of sedation, or a continuous infusion of anesthetic, which can result in respiratory suppression. For this reason, monitoring of ETCO2 has commonly been used as a surrogate for unobstructed and adequate ventilation, i.e. air exchange . In the case of MAC, the breathing system is not closed as it is with an endotracheal tube used in general anesthesia (GA). As such, the value of ETCO2 recorded may not be exactly accurate due to escape of ETCO2 to the environment. Nonetheless, the presence of a capnography waveform is reassuring and is routinely used in our healthcare system as a surrogate for ventilation during MAC, as several studies have shown ETCO2 to accurately detect airway obstruction.

When airway obstruction does occur during MAC, anesthesia providers often are able to place a patient in the "sniffing position". This position aligns the airway in such a way as to minimize obstruction caused by the relaxation of the tongue and upper airway reflexes during anesthesia. If this cannot be achieved stably and safely, the decision is made to convert the anesthesia to GA. The incidence of this is typically low, but involves higher risk, as airway intervention in the way of intubation with an endotracheal tube to facilitate mechanical ventilation is needed, as well as establishment of a deeper plane of anesthesia with medications that can result in hypotension and other medication-related complications.

The Stable Airway Management (SAM) device is designed to maintain the sniffing position effectively and prevent the patient from sliding back into an obstructed airway position. This can reduce the incidence of apnea, which can result in oxygen desaturation if not treated quickly by an attentive anesthesia provider. One study found the incidence of apnea (defined as > 20 seconds) during MAC to be as high as 26%, and a subsequent study by the same group found the incidence to be even higher, 49.5% of 99 patients demonstrating > 60 seconds apnea during MAC sedation cases. Doing this effectively would alleviate the need for frequent airway manipulation during the procedure, which risks awakening the patient, disrupting the procedure, and takes attention away from monitoring the other complex aspects of anesthetic care.

Kent CD, Metzner JI, Domino KB. Anesthesia hazards: lessons from the anesthesia closed claims project. International anesthesiology clinics. 2020 Jan 1;58(1):7-12.

Weaver, J. "The latest ASA mandate: CO2 monitoring for moderate and deep sedation." Anesthesia Progress. 2011: 111-112.

Nishino T. Physiological and pathophysiological implications of upper airway reflexes in humans. The Japanese journal of physiology. 2000;50(1):3-14.

Soto RG, Fu ES, Vila Jr H, Miguel RV. Capnography accurately detects apnea during monitored anesthesia care. Anesthesia & Analgesia. 2004 Aug 1;99(2):379-82.

Tobias, JD. End-tidal carbon dioxide monitoring during sedation with a combination of midazolam and ketamine for children undergoing painful, invasive procedures. Pediatric emergency care. 1999 Jun 1;15(3):173-5.

Poirier MP, Del-Rey JA, McAneney CM, Digiulio GA. Utility of monitoring capnography, pulse oximetry, and vital signs in the detection of airway mishaps: a hyperoxemic animal model. The American journal of emergency medicine. 1998 Jul 1;16(4):350-2.

Isono S, Tanaka A, Ishikawa T, Tagaito Y, Nishino T. Sniffing position improves pharyngeal airway patency in anesthetized patients with obstructive sleep apnea. The Journal of the American Society of Anesthesiologists. 2005 Sep 1;103(3):489-94.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
We hypothesize that the Stable Airway Management device (SAM) will prove safe and result in a 20% lower incidence of apnea compared with standard of care. It is furthermore hypothesized that there will be equal or fewer conversions from monitored anesthesia care (MAC) to general anesthesia for airway-related problems, for patients using the SAM.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The goal of the research at hand is to determine if the SAM can be used safely, and as a useful adjunct in anesthesia care.

   The specific aims of this study are the following:
   1. To study the safety and feasibility of the use for the Stable Airway Management (SAM) device in monitored anesthesia care (MAC) cases.
   2. To study the incidence of airway obstruction resulting in apnea during MAC with use of the SAM vs. standard of care.

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

   The importance of the study lies in the knowledge of whether the SAM can be safely used in adult patients undergoing MAC in the supine position. Furthermore, we plan to examine if its use can help reduce the incidence of airway obstruction and consequently apnea, which has significant risk, including oxygen desaturation and impaired ventilation, which can result in severe hypoxemia and even death. This could provide significant improvement in safety in anesthesia care.

5. * **Describe any potential for direct benefits to participants in this study:**
Potential direct benefits to study participants include airway stability during MAC that reduces the risk for airway obstruction and apnea, and therefore need for manipulation of the airway or interruption of their stable anesthetic.

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:**
If proven successful, utilization of the SAM will provide an increased margin of safety for patients during monitored anesthesia care cases, allowing for faster procedure times and decreased medical costs.

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

ID: HM20022338 View: SF2 - Study Population

Study Population

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

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

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   40

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

This will be a single-center project conducted at VCU.

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:**
The overarching goal of this pilot treatment study is to obtain estimates of the means and variances of all study measures to calculate effect sizes to facilitate a power analysis for future extramurally funded clinical trials. The method of setting the pilot trial sample size in order to minimize the overall sample size of a pilot and main trial together was described by Kieser and Wassamer. They applied an 80% upper confidence limit approach to the sample size calculation and found that a pilot trial sample size between 20 and 40 would minimize the overall sample size for a main study sample size of 80-250, corresponding to standardized effect sizes of 0.4 and 0.7, for 90% power based on a standard sample size calculation. We will employ the same approach here. Two randomized groups will be examined, Standard of Care versus SAM deployment. Each group will have an n=20. In total, there will be 40 total participants, where 20 participants receive the standard of care, and 20 receive SAM deployment.

4. * **List the study inclusion criteria:**
1. Patients undergoing MAC anesthesia in the supine position
2. patients able to give informed consent

5. * **List the study exclusion criteria:**
1. Age < 18 years
2. Non-elective procedures
3. Surgery duration > 180 minutes
4. Presence of a cervical spine injury, instability, or cervical spine collar
5. Patients with airway, facial, or other anatomy deemed inappropriate for SAM use by anesthesiologist
6. General anesthesia as primary anesthetic
7. Prisoners
8. Pregnant women

Vulnerable subjects: No vulnerable patient populations will be enrolled in this study.

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 reason for not including pregnant women in this pilot study is because the patient population for this initial study is elective surgical patients, for which most pregnant women are excluded, independent of this study design - pregnant women requiring surgery are almost always urgent/emergent and would not fit criteria for this study.

A cesarean section is in fact many times elective, but MAC is typically not used and the patient is awake, also precluding inclusion in this study.

ID: HM20022338 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
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Click Continue below to go to the next section

ID: HM20022338 View: SF2 - Study Procedures

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   We hypothesize that the Stable Airway Management device (SAM) will prove safe and result in a 20% lower incidence of apnea compared with standard of care. It is furthermore hypothesized that there will be equal or fewer conversions from monitored anesthesia care (MAC) to general anesthesia for airway-related problems, for patients using the SAM.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The goal of the research at hand is to determine if the SAM can be used safely, and as a useful adjunct in anesthesia care.

   The specific aims of this study are the following:
   1. To study the safety and feasibility of the use for the Stable Airway Management (SAM) device in monitored anesthesia care (MAC) cases.
   2. To study the incidence of airway obstruction resulting in apnea during MAC with use of the SAM vs. standard of care.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
   - [ ] E-mail invitations
   - [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
   - [ ] Flyers, Mailed Letters or Newspaper/TV/Radio Ads
   - [ ] TelegRAM announcements
   - [ ] Website text
   - [ ] Study-specific web sites (provide the design and text)
   - [ ] Social Media
   - [ ] EPIC MyChart Patient Portal research study descriptions
   - [ ] Psychology Research Participant Pool (SONA) study descriptions
   - [ ] Scripts for announcements made to groups
   - [ ] Other recruitment material
   - [x] **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.
Patients undergoing monitored anesthesia care (MAC) cases on the surgical schedule will be identified by the clinical research coordinator (CRC). The CRC will screen for potential participants using the electronic medical record, examining the clinic schedule prior to patients' preoperative clinic appointments, and looking for the expected surgical procedures that would warrant MAC. The patient's name, date of surgery, and date of birth will be collected as part of this CRC screening process. The CRC will consent patients during their preoperative clinic appointment prior to surgery and will ensure that participants do not meet the exclusion criteria prior to consent.

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
This study is a non-blinded, randomized controlled trial in which participants undergoing MAC (monitored anesthesia care) for scheduled surgical procedures will be randomized to two arms, with the research coordinator (CRC) using an electronic randomizer to assign participants into the two study arms.

The study investigators will conduct in-person training sessions with the SAM device for anesthesia staff (anesthesiologists and nurse anesthetists administering anesthetic care) prior to their care of patients who are consented for the study. The CRC will be trained by the investigators in use, deployment, and troubleshooting of the device., and will assist during these sessions. These training sessions will take place prior to the initiation of patient enrollment in the study, and the investigators will be available to help with any questions from anesthesia providers. We will document a list of anesthesia providers who have completed the training, and only these providers will be permitted to use the SAM device for patients enrolled in the study. The CRC and investigators will be readily available to anesthesia providers for any issues that arise during study procedures as well. All procedural care related to the study will be in a standard of care operating room setting in which these surgical procedures routinely take place.

Each arm will undergo standard anesthetic procedures for MAC, which include standard monitoring of blood pressure, SpO2, electrocardiogram monitoring, etCO2 waveform capnography, and the availability of temperature monitoring. The medications used to achieve an adequate MAC anesthetic will be at the discretion of the anesthesia provider, and medications used will be noted. One arm, the intervention arm, will aim for maintenance of a patent airway with the SAM device, while the other will be a standard of care (SOC) arm. In the intervention arm, the anesthesia provider will be given a SAM device that will be used to maintain the patient's head in a slight sniffing position, and adjust as necessary to maintain the desired head position that is optimal for a patent airway, thereby facilitating unobstructed breathing. In the SOC arm, the same goal will be maintained, but with traditional methods, which often include pillows or towels, if anything. If the SAM use becomes unsafe for a given subject, care can be converted to standard of care, at the discretion of the anesthesia provider, and reason for cessation of use will be documented and reviewed by the DSMB. We will measure the number of apneic events, defined as > 20 seconds apnea as detected by capnography, per 15-minute interval and total number per patient, between the two arms, as well as the incidence of conversion from

MAC to general anesthesia for airway-related complications. We will also have anesthesia providers document the number of head/airway manipulations needed per 15-minute intervals.

The safety of the SAM over the course of the study will be determined by comparison to the SOC, specifically regarding number of conversions to general anesthesia for airway-related complications. This data will be reviewed by the DSMB. The safety of continuing to use the SAM during a given procedure for a study participant in the SAM arm will also be at the discretion of the anesthesia provider, specifically looking at repeated oxygen desaturation or inability to maintain the airway with the SAM, that would necessitate use of a different airway management tool.

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.).
   All study activities are being performed exclusively for research purposes.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
   If potential participants choose not to participate in this study, they will undergo their scheduled surgical procedure and not be enrolled 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: HM20022338 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
   - [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
   - [ ] Specimen/biological sample collection
   - [ ] None of the Above

2. * **Select all of the following types of interactions that apply to this study (selections will branch):**

- [ ] Surveys / Questionnaires /Written responses to questions (including data entry)
- [ ] Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)
- [ ] Interviews / Focus Groups / Verbal responses to questions
- [ ] Audio / Video recording or photographing participants
- [ ] Observations
- [ ] Passive Internet data collection (i.e. passively observing online behavior)
- [ ] Educational Settings/Assessments/Procedures
- [x] **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)**
   - [ ] 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: HM20022338 View: SF2 - Bio-Medical Device Details

Bio-Medical Device Details

1. * **Select the type of device :**
   - [ ] 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
   - [x] **Investigational device**
   - [ ] Humanitarian Use Device (HUD)

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

Device	Manufacturer	Device Risk	IDE	IDE Holder
Stable Airway Management	Atlantic Wave LLC	Non-Significant Risk	Abbreviated IDE	Not Required

3. * **Describe how the device will be stored and controlled.**
   All Stable Airway Management (SAM) devices will be controlled by the clinical research coordinator and stored in their office.

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 IDE exemption under under 21 CFR 812.2(c), upload one of the following documents for each applicable device:
- A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c).
- External sponsor's protocol including IDE exemption information
- Communication from the external sponsor verifying the IDE exemption
- Communication from the FDA with verification of IDE exemption

B2. Upload at least one of the following documents for each Significant Risk medical device:
- 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 each Non-Significant Risk medical device:
- 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	SAM Consent Form	Consent Form- IRB Clean Version 10-4-21.pdf	0.06	11/4/2021 12:54 PM	David Cohen	Consent/Assent/Information Sheet	Yes
View	SAM Device Photograph 2 (without final pads)	SAM device photograph 2.jpeg	0.01	10/12/2021 9:40 PM	Vishal Yajnik	Other	Not Applicable
View	Non-Significant Risk Justification for SAM - Revised	Non-Significant Risk Justification for SAM - Revised.docx	0.01	10/12/2021 9:04 PM	David Cohen	Other	Yes
View	IDE Justification for SAM	IDE Justification for SAM.docx	0.01	10/12/2021 9:03 PM	David Cohen	Other	Not Applicable
View	Post-Procedure Safety Follow Up 10-4-21	Post-Procedure Safety Follow-Up Phone Script 10-4-21.docx	0.01	10/4/2021 3:41 PM	David Cohen	Study reminders/communications	Yes
View	OSP Memo Regarding Industry Coverage in Case of Injury	Cohen Yajnik Atlantic IRB SIL Memo (FP00015821).pdf	0.01	9/13/2021 3:20 PM	David Cohen	Other	Not Applicable
View	Clinical Trial Agreement	RV00020402 SAM CTA Contract with Exhibits 06.29.2021 VCU Template (VCUmef Edits 9.8.21).docx	0.01	9/13/2021 3:16 PM	David Cohen	Other	Not Applicable

View	Cohen Biosketch	Cohen Biosketch.docx	0.01	6/28/2021 11:33 AM	David Cohen	CV/Biosketch	Not Applicable
View	Vishal Yajnik CV	Yajnik CV 2021.docx	0.01	6/27/2021 3:49 PM	Vishal Yajnik	CV/Biosketch	Yes
View	SAM Description	Stable Airway Management Device Description-IRB.docx	0.01	6/26/2021 5:17 PM	David Cohen	Other	Not Applicable

ID: HM20022338 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.
   Data will be obtained from the patient's medical record in Cerner/Epic. A patient's age, height, weight, BMI, sex, medications, prior medical conditions and prior surgeries will be recorded.

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.**
   The clinical research coordinator will assign a code to all study participants, maintaining the key in a locked and secure location. No other study participants will have access to the key.

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: HM20022338 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

2. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
   There are no costs that are study-related, only costs related to the surgery for which the participant is presenting. These would be covered by their insurance or whichever method they are using to pay for their medical services.

3. * **Describe any procedures, therapy, lab work, x-rays, drugs, or devices, etc that are considered standard of care and will be charged to the participant or their insurance.**
   The surgical procedure, related imaging, laboratory work, anesthesia care costs are the costs that the participant and/or their insurance provider will bear. These are standard of care for patients undergoing surgical procedures and deviation from this will not be expected for the purposes of the proposed study.

4. * **Describe the process to determine whether participants' insurance will cover the expenses.**
   The participant's insurance will not be covering the costs of the SAM device or its use in this study. How the participant's insurance will cover other medical expenses related to their surgery is beyond the scope of the study or the investigators.

ID: HM20022338 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
   n/a

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

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

ID: HM20022338 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: HM20022338 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: HM20022338 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	Adults	Signed Consent by Participant Short Form Consent (limited applicability)	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	Written informed consent will be obtained by study team prior to enrollment in the study, in the preoperative anesthesia clinic and preoperative neurosurgery clinic. These clinic appointments are usually well in advance of the scheduled procedure	The consent will not be obtained by anesthesia providers caring for the potential participant, but rather by the study coordinator or study team member. It will be made clear to the patient that the SAM device is for research	Participants will be given as much time as is necessary to make their decision.	n/a

						and will allow for participants to have enough time to consider their enrollment in the study.	purposes only and that participating or not participating in the study will in no way impact their anesthetic or surgical care.		
View	Medical Record Screening for Recruitment	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent	Not using electronic signature platforms	n/a	n/a	n/a	n/a

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

ID: HM20022338 View: SF2 - Waiver of Some or All Elements of Consent

Waiver of Some or All Elements of Consent

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

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
Medical Record Screening for Recruitment	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	N/A: Requesting Waiver of Consent		n/a	n/a	n/a

1. * **For each group listed at the top of this page, describe which elements of informed consent you are waiving or altering.**

   - To request a waiver or alteration of SOME elements of informed consent, describe each of the elements that you wish to waive. See the help text for a list of elements, and copy/paste the descriptions of the elements (not just the element numbers) into this response.
   - To waive ALL elements of informed consent, state "All elements of informed consent" in this response.
   Medical Records of incoming patients into the pre-operative anesthesia clinic will be reviewed in order to determine eligibility for study enrollment. Patients who will undergo procedures involving monitored anesthesia care in a supine position will be approached by the clinical research coordinator and subsequently fully consented prior to enrollment into the study. Because this is a medical records screening to determine patient eligibility, we request a waiver for all elements of informed consent for this screening process.

2. * **Will you be waiving parental permission for wards of the state (and/or a Legally Authorized Representative's consent) in any of the consent groups at the top of this page:**
   - ○ Yes
   - ● **No**

3. * **Is this study conducted by or subject to the approval of State or Local Government and designed to study,**

evaluate, or otherwise examine public benefit or service programs:

○ Yes

● **No**

4. * **Explain how the research involves no more than minimal risk to the participants (Alternative question phrasing: How do the risk(s) of the research activity for which consent is being waived compare to the risks a person might reasonably experience in normal everyday life?)::**
Patients who are approached by the clinical research coordinator and who agree to participate in the study will be fully consented. We are requesting a waiver to allow the clinical research coordinator to look up medical records during pre-operative anesthesia clinic in order to determine if a patient is eligible for the study. No information will be recorded or saved as a function of this screening process if the patient is not a candidate for enrollment in the study.

5. * **Explain how the research could not practicably be carried out without the waiver or alteration (Alternative question phrasing: Why would obtaining consent from participants make the study not achievable or not viable?):**
Consent will be obtained from participants. We request a waiver to prescreen medical records during the pre-operative anesthesia clinic in order to determine which patients are candidates for enrollment.

6. * **Explain why this study can only be carried out using identifiable or de-identified information/biospecimens. - Studies with Department of Justice funding may state "Not applicable."**
(Alternative question phrasing: Why would it be impossible to conduct the study using only anonymous information/biospecimens?).
The clinical research coordinator will pre-screen medical records during the pre-operative anesthesia clinic. If patients are eligible for enrollment, the crc must know the patient's name and id number in order to speak to them regarding enrollment in the study.

7. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants (Alternative question phrasing: Will this consent waiver violate any of the participant's rights or adversely affect their welfare - why or why not?):**
The waiver won't adversely affect the rights or welfare of participants because no information will be recorded as a function of this pre-screening process if the subject is not eligible for enrollment. The only purpose of the pre-screening for recruitment is for the crc to identify appropriate patients to speak to regarding study enrollment. All study participants will be fully consented prior to enrollment.

8. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not:**
Study participants will be provided pertinent information in the pre-operative anesthesia clinic. Because a pre-screening of medical records will determine subject eligibility, there is no reason to provide additional information to patients who will not be approached regarding enrollment in the study.

ID: HM20022338 View: SF2 - Short Form Consent

Short Form Consent

Consent groups that require a short form consent document:

Groups	Types	Waivers	Roles	Roles Other	Consent	Decision	Status Change
Adults	Signed Consent by Participant Short Form Consent (limited applicability)	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator		Written informed consent will be obtained by study team prior to enrollment in the study, in the preoperative anesthesia clinic and preoperative neurosurgery clinic. These clinic appointments are usually well in advance of the scheduled procedure and will allow for participants to have enough time to consider their enrollment in the study.	Participants will be given as much time as is necessary to make their decision.	n/a

1. * **A Short Form written consent stating that the elements of consent have been presented orally to the participant or Legally Authorized Representative 45 CFR 46.117(b)(2). Does the PI certify that all of the following will occur:**
   1) A witness will be present to observe the consent process
   2) The Short Form will be signed by the participant or the Legally Authorized Representative
   3) The witness will sign both the Short Form and the Summary
   4) The person obtaining consent will sign the Short Form and the Summary
   5) The participant will sign the Short Form
   6) A copy of the Summary and the Short Form will be given to the participant or Legally Authorized Representative
   - (●) **Yes**
   - ( ) No

2. * **Explain why you are requesting to use a short form consent form:**
   We anticipate that less than 5% of our study population will be of limited English proficiency. In order to allow for study participation by those of limited English proficiency, a short form consent in their native language will be provided, along with translation services to translate the entire English language consent form. Both the original consent form, along with the short form consent will be signed and witnessed.

ID: HM20022338 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: HM20022338 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.

There is a minimal risk of minor pain or discomfort following the procedure resulting from the foam pad placement.

There is minimal risk for the loss of confidentiality and privacy due to the measures that will be taken to maintain privacy and security for data as well as the minimal PHI needed to conduct the study.

There is a minimal risk of jaw and/or neck pain.

SAM may not be as good as usual approach. There is a minimal chance that this is true.

There is minimal chance that as yet unknown risks may occur.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
The anesthesia provider will be trained how to properly deploy the device by the clinical research coordinator, ensuring appropriate pad placement. The foam pads are thick enough and will provide enough cushion to prevent soreness along the body of the mandible, where the pads will be deployed.

   The loss of confidentiality and privacy will be mitigated by deidentifying all study participants and maintaining all study documents including patient consent forms under lock and key.

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):**
Not applicable.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
Anesthesia expertise in airway management will be directly present for all subjects throughout study procedures and interventions as needed to ensure medical safety will be performed at the discretion of the anesthesia care team, which includes the provider and attending anesthesiologist.

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.:**
The study team would withdraw any subjects who demonstrate an inability to comply the study protocol, at the discretion of the anesthesia provider, who will be at their bedside throughout the anesthetic.

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:**
Three days following their procedure, the clinical research coordinator will follow up with the study participants and ask the following questions:

   - Do you have any jaw pain?
   - Do you have any neck pain?
   - Do you have any head pain?

   A telephone script that the CRC will use during these interactions has been uploaded.

   If 20% of patients in the SAM intervention arm report pain or neuralgia to their jaw/neck following the procedure, this will trigger a stop with immediate review of 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]**
   - [x] **DSMB**
   - [ ] DSMP
   - [ ] No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe the composition and affiliations of the DSMB:**
   The DSMB, headed by Dr. Nirvik Pal, will be comprised of two attending faculty anesthesiology physicians (including Dr. Pal) from VCU Health, and a biostatistician.

9. * **Describe the frequency or schedule for DSMB review of data:**
   The DSMB will meet every month during the study period.

10. * **Describe what data (blinded or unblinded) the DSMB will review.:**
    DSMB will review (unblinded) protocol compliance and adverse events.

ID: HM20022338 View: SF2 - Privacy

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

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

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

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [x] **Asking the participant if they are comfortable answering questions in that location**
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**

- [x] **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.):**
- [x] **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.**
- [ ] Obtaining permission prior to sending text messages
- [x] **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.)**
   - [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
   - [ ] Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform
   - [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
   - [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
   - [ ] Other protections not listed in this question – describe below

6. * **If "other protections" was selected in one or more of the questions above, describe all the other way(s) that the research team will protect participants' privacy. See the help text for additional guidance.**
   n/a

ID: HM20022338 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**
   - [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
   - [ ] Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy
   - [ ] Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no paper research materials

2. * **Protections for research specimens:**
   - [ ] Maintaining control of specimens at all times, including when at an off-campus location
   - [ ] Storing specimens in a secure location accessible only to authorized study personnel
   - [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
   - [ ] Final destruction of specimens will be devoid of any identifiable information
   - [ ] Other protection not listed in this question – describe below
   - [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)**
   - [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
   - [x] **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 Healthapproved 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 studys paper and electronic research data and/or physical specimens will be stored and how they will be secured from improper use and disclosure.**
   n/a
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).**
   No data containing HIPAA identifiers will be released to people or groups outside of the study team.
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)
   - [x] **Ages over 89 (age under 89 is not an identifier)**
   - [x] **Phone Numbers**
   - [ ] Facsimile Numbers
   - [x] **E-mail Addresses**
   - [x] **Medical Record Numbers**
   - [ ] Device Identifiers
   - [ ] Biometric Identifiers

- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

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

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

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

   See the help text for guidance.
   Following study enrollment, the clinical research coordinator will assign all study participants a sequential number. The key that links the subject ID with direct identifiers will be maintained by the clinical research coordinator alone as they will be tasked with enrolling all patients. The key will be stored in the clinical research coordinator's office under lock and key. The key will be destroyed once the study has been completed and all data records have been collected and de-identified.

ID: HM20022338 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:**
   - [x] **Immediately destroy the information and identifiers (no data collected)**
   - [ ] Immediately destroy the identifiers connected with the data (anonymization)
   - [ ] Store until the end of study & then destroy
   - [ ] Use as "screening failure" data by members of the study team
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain and use the identifiable information
   - [ ] Other
   - [ ] N/A - study does not require screening procedures

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that**

it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No - see help text)

- ○ Yes
- ● **No**

3. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - ○ Stored indefinitely with identifiers removed
   - ○ Stored indefinitely with identifiers attached
   - ● **Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements**
   - ○ Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ○ Other

ID: HM20022338 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 individual-level information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (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.)

- [x] **Will not use information/specimens for purposes beyond this study.**
- [ ] Not sure and will submit an amendment when known
- [ ] Other use(s) of individual-level information in a way not listed above

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.**

☐ 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: HM20022338 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: HM20022338 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: HM20022338 View: SF2 - Populations with Special Considerations

Populations with Special Considerations

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

   a) Specifically included in this study or

   b) Discernable in the research data/specimens.

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

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

ID: HM20022338 View: SF2 - Limited English Proficiency

Limited English Proficiency

1. * **Describe how Non-English speaking or limited English proficiency participants will be able to communicate with the study staff at enrollment and throughout the study. Include the following information:**
   - how the initial informed consent process will be handled
   - how the research team plans to interact with LEP participants throughout the conduct of the study
   - whether there will be a qualified interpreter or assistive translational devices available
   - whether the study consent document will be translated or a short form consent document will be used
   - the names of the individuals or professional groups who will provide oral interpretation or written translation services
   If potential study participants have limited English proficiency, the clinical research coordinator will use VCU Health language and communication services to ensure that the patient fully understands the study, and fully consents to be a participant in the study. Free interpreters are available to help the patient and health care providers communicate with one another. A two-handset telephone is available to assist limited-English-proficient patients and their families in communicating with staff and health care professionals. The study consent document will not be translated into languages. A short form consent in the participant's native language will also be used.

2. * **Describe any additional risks or harms to the individual because of their limited English proficiency and how these will be minimized.**
   Apart from ensuring full understanding of consent documents, all other study participation will be part of the normal standard of care that they receive by their health care providers.

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

ID: HM20022338 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: HM20022338 View: SF2 - Study Funding

Study Funding

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

2. **Is this study already funded:**
   - ● **Yes**
   - ○ No

3. * **Select all funding sources for this study (pending or awarded):**
   - ☑ **Industry**
   - ☐ Direct Federal
   - ☐ Indirect Federal
   - ☐ State/Local Government
   - ☐ Non-Profit - Sponsored Project
   - ☐ Non-Profit - Gift
   - ☐ Internal Grant
   - ☐ Investigator/Departmental Funds
   - ☐ None
   - ☐ Other

4. **Since Industry was selected above, explain why this study is not being submitted to Western IRB.**
   This study is an investigator-initiated study with material and study support provided by an industry sponsor. We are submitting to VCU's IRB rather than a Western IRB based on the guidance of IRB staff.

5. **Select all related proposals:**

RAMS-SPOT ID# (FP/PT/PD#)	Sponsor	PI	Title	Status	Start	End
FP00015821	Atlantic Wave Holdings	Vishal Yajnik	Use of Stable Airway Management Device in Monitored Anesthesia Care	Award Received		

6. **If grant congruence review is requested, upload the entire grant proposal (exclusive of budget and appendices).**

   If Industry was selected above, upload the OSP Subject Injury Language Memo or other documentation from OSP approving the consent form's subject injury language.

ID: HM20022338 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	SAM Consent	Consent Form- IRB	0.06	11/4/2021	David	Consent/Assent/Information	Yes

	Form	Clean Version 10-4-21.pdf		12:54 PM	Cohen	Sheet	
View	SAM Device Photograph 2 (without final pads)	SAM device photograph 2.jpeg	0.01	10/12/2021 9:40 PM	Vishal Yajnik	Other	Not Applicable
View	Non-Significant Risk Justification for SAM - Revised	Non-Significant Risk Justification for SAM - Revised.docx	0.01	10/12/2021 9:04 PM	David Cohen	Other	Yes
View	IDE Justification for SAM	IDE Justification for SAM.docx	0.01	10/12/2021 9:03 PM	David Cohen	Other	Not Applicable
View	Post-Procedure Safety Follow Up 10-4-21	Post-Procedure Safety Follow-Up Phone Script 10-4-21.docx	0.01	10/4/2021 3:41 PM	David Cohen	Study reminders/communications	Yes
View	OSP Memo Regarding Industry Coverage in Case of Injury	Cohen Yajnik Atlantic IRB SIL Memo (FP00015821).pdf	0.01	9/13/2021 3:20 PM	David Cohen	Other	Not Applicable
View	Clinical Trial Agreement	RV00020402 SAM CTA Contract with Exhibits 06.29.2021 VCU Template (VCUmef Edits 9.8.21).docx	0.01	9/13/2021 3:16 PM	David Cohen	Other	Not Applicable
View	Cohen Biosketch	Cohen Biosketch.docx	0.01	6/28/2021 11:33 AM	David Cohen	CV/Biosketch	Not Applicable
View	Vishal Yajnik CV	Yajnik CV 2021.docx	0.01	6/27/2021 3:49 PM	Vishal Yajnik	CV/Biosketch	Yes
View	SAM Description	Stable Airway Management Device Description-IRB.docx	0.01	6/26/2021 5:17 PM	David Cohen	Other	Not Applicable

ID: HM20022338 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	David Cohen	Co/Sub-Investigator		Project Coordination Study Design		Experience - Research Experience - Clinical		yes
View	Vishal Yajnik	Principal Investigator		Project Coordination Study Design		Experience - Research Experience - Clinical Education and/or Professional Preparation		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: HM20022338 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 project

◯ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
   Non-financial Interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - 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)
   Vishal Yajnik and David Joshua Cohen serve as unpaid advisory board members, as product consultants, for the SAM device. They both have a royalty agreement with Atlantic Wave Holdings, LLC, the holding company that owns the device.

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.

ID: HM20022338 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**

    Based upon your responses, this study will be routed to the VCU Scientific Review Committee (SRC) when it is submitted. After SRC review is completed, the IRB will receive the study.

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

ID: HM20022338 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.**
A patient's age, sex, weight, BMI, medications, and prior medical history will be obtained in this research.

3. * **Describe the source(s) of the protected health information (e.g. which clinical databases):**
Information will be obtained from Cerner/Epic.

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):**
   - [x] **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: HM20022338 View: SF2 - De-Identified Data

De-Identified Data

1. * **The PI certifies that the data collected or used in this study does not contain any of the following identifiers and the PI does not have access to a key to link a code to the identifying information:**
   1) Names
   2) Geographic Locators Below State Level
   3) Social Security Numbers
   4) Dates, except years and ages >89
   5) Phone Numbers
   6) Facsimile Numbers
   7) Email Addresses
   8) Medical Record Numbers
   9) Device Identifiers
   10) Biometric Identifiers
   11) Web URLs
   12) IP Addresses
   13) Account numbers
   14) Health Plan Numbers
   15) Full Face Photos or Comparable Images
   16) License /Certificate Numbers
   17) Vehicle ID Numbers
   18) Other Unique Identifier
   - ○ Yes
   - ● **No**
2. * **Select which method of de-identification applies to the data used for this study.**
   - ● **All Identifiers Removed (Safe Harbor)**
   - ○ Expert determination Verifying No Possibility of Re-Identification
3. **If statistical analysis will be done to determine data is not identifiable, upload attestation from the statistician.**

ID: HM20022338 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: HM20022338 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	SAM Consent Form	Consent Form- IRB Clean Version 10-4-21.pdf	0.06	11/4/2021 12:54 PM	David Cohen	Consent/Assent/Information Sheet	Yes
View	SAM Device Photograph 2 (without final pads)	SAM device photograph 2.jpeg	0.01	10/12/2021 9:40 PM	Vishal Yajnik	Other	Not Applicable
View	Non-Significant Risk Justification for SAM -	Non-Significant Risk Justification for SAM - Revised.docx	0.01	10/12/2021 9:04 PM	David Cohen	Other	Yes

	Revised						
View	IDE Justification for SAM	IDE Justification for SAM.docx	0.01	10/12/2021 9:03 PM	David Cohen	Other	Not Applicable
View	Post-Procedure Safety Follow Up 10-4-21	Post-Procedure Safety Follow-Up Phone Script 10-4-21.docx	0.01	10/4/2021 3:41 PM	David Cohen	Study reminders/communications	Yes
View	OSP Memo Regarding Industry Coverage in Case of Injury	Cohen Yajnik Atlantic IRB SIL Memo (FP00015821).pdf	0.01	9/13/2021 3:20 PM	David Cohen	Other	Not Applicable
View	Clinical Trial Agreement	RV00020402 SAM CTA Contract with Exhibits 06.29.2021 VCU Template (VCUmef Edits 9.8.21).docx	0.01	9/13/2021 3:16 PM	David Cohen	Other	Not Applicable
View	Cohen Biosketch	Cohen Biosketch.docx	0.01	6/28/2021 11:33 AM	David Cohen	CV/Biosketch	Not Applicable
View	Vishal Yajnik CV	Yajnik CV 2021.docx	0.01	6/27/2021 3:49 PM	Vishal Yajnik	CV/Biosketch	Yes
View	SAM Description	Stable Airway Management Device Description-IRB.docx	0.01	6/26/2021 5:17 PM	David Cohen	Other	Not Applicable

ID: HM20022338 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: HM20022338 View: Copy of Bio-Med Devices

Bio-Medical Devices

1. * **Name:**
   Stable Airway Management
2. * **Manufacturer:**
   Atlantic Wave LLC
3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Non-Significant Risk
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).

   Abbreviated IDE
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.**

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   SAM Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent Form- IRB Clean Version 10-4-21.pdf(0.06)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   SAM Device Photograph 2 (without final pads)
2. * **Type:**
   Other
3. * **File:**
   SAM device photograph 2.jpeg(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Non-Significant Risk Justification for SAM - Revised
2. * **Type:**
   Other
3. * **File:**
   Non-Significant Risk Justification for SAM - Revised.docx(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   IDE Justification for SAM
2. * **Type:**
   Other
3. * **File:**
   IDE Justification for SAM.docx(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Post-Procedure Safety Follow Up 10-4-21
2. * **Type:**
   Study reminders/communications
3. * **File:**
   Post-Procedure Safety Follow-Up Phone Script 10-4-21.docx(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   OSP Memo Regarding Industry Coverage in Case of Injury
2. * **Type:**
   Other
3. * **File:**
   Cohen Yajnik Atlantic IRB SIL Memo (FP00015821).pdf(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Clinical Trial Agreement
2. * **Type:**
   Other
3. * **File:**
   RV00020402 SAM CTA Contract with Exhibits 06.29.2021 VCU Template (VCUmef Edits 9.8.21).docx(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

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

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Vishal Yajnik CV
2. * **Type:**
   CV/Biosketch
3. * **File:**

Yajnik CV 2021.docx(0.01)

ID: HM20022338 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   SAM Description
2. * **Type:**
   Other
3. * **File:**
   Stable Airway Management Device Description-IRB.docx(0.01)

ID: HM20022338 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Adults
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:**

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

Written informed consent will be obtained by study team prior to enrollment in the study, in the preoperative anesthesia clinic and preoperative neurosurgery clinic. These clinic appointments are usually well in advance of the scheduled procedure and will allow for participants to have enough time to consider their enrollment 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.):**
The consent will not be obtained by anesthesia providers caring for the potential participant, but rather by the study coordinator or study team member. It will be made clear to the patient that the SAM device is for research purposes only and that participating or not participating in the study will in no way impact their anesthetic or surgical care.

9. * **How much time will participants be given to make a decision:**
Participants will be given as much time as is necessary to make their decision.

10. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
n/a

ID: HM20022338 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Medical Record Screening for Recruitment

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
- [x] **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:**

- [ ] 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
- [x] **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:**

n/a

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.):**
n/a

9. * **How much time will participants be given to make a decision:**
n/a

10. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
n/a

ID: HM20022338 View: Personnel

Personnel

1. * **Name:**
David Cohen

2. * **Is this individual a 'COI Investigator'?**

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

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

- (●) **Yes**
- ( ) No

3. * **Roles:**

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

- [ ]
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

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

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

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

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

7. **Additional or Emergency Phone:**
   210-355-5862

ID: HM20022338 View: Personnel

Personnel

1. * **Name:**
   Vishal Yajnik

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

- [x] **Project Coordination**
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

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

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

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

7. **Additional or Emergency Phone:**
   856-520-1204