Date: Wednesday, August 31, 2016 3:46:04 PM Print Close

ID: HM20007902 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Praveen Dharmapalan Prasanna

2. * **Study Title:**
   General anesthesia with endotracheal tube versus laryngeal mask airway in patients undergoing catheter ablation for atrial fibrillation, a non-inferiority trial

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision:**
   - ○ Yes
   - ◉ **No**

4. **Select any associated VCU IRB protocols:**

ID	PI
HM20007696	Praveen Dharmapalan Prasanna

[redacted]

ID: HM20007902 View: SF - Research Determination

Research Determination

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

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

ID: HM20007902 View: SF - Federal Regulations

Federal Regulations

1. * **Is this a Clinical Trial:**
   - ◉ **Yes**
   - ○ No

2. **Is this an Applicable Clinical Trial that must be registered and reported to clinicaltrials.gov:**
   - ◉ **Yes**
   - ○ No

3. * **Is this a FDA regulated study:**
   - ○ Yes
   - ◉ **No**

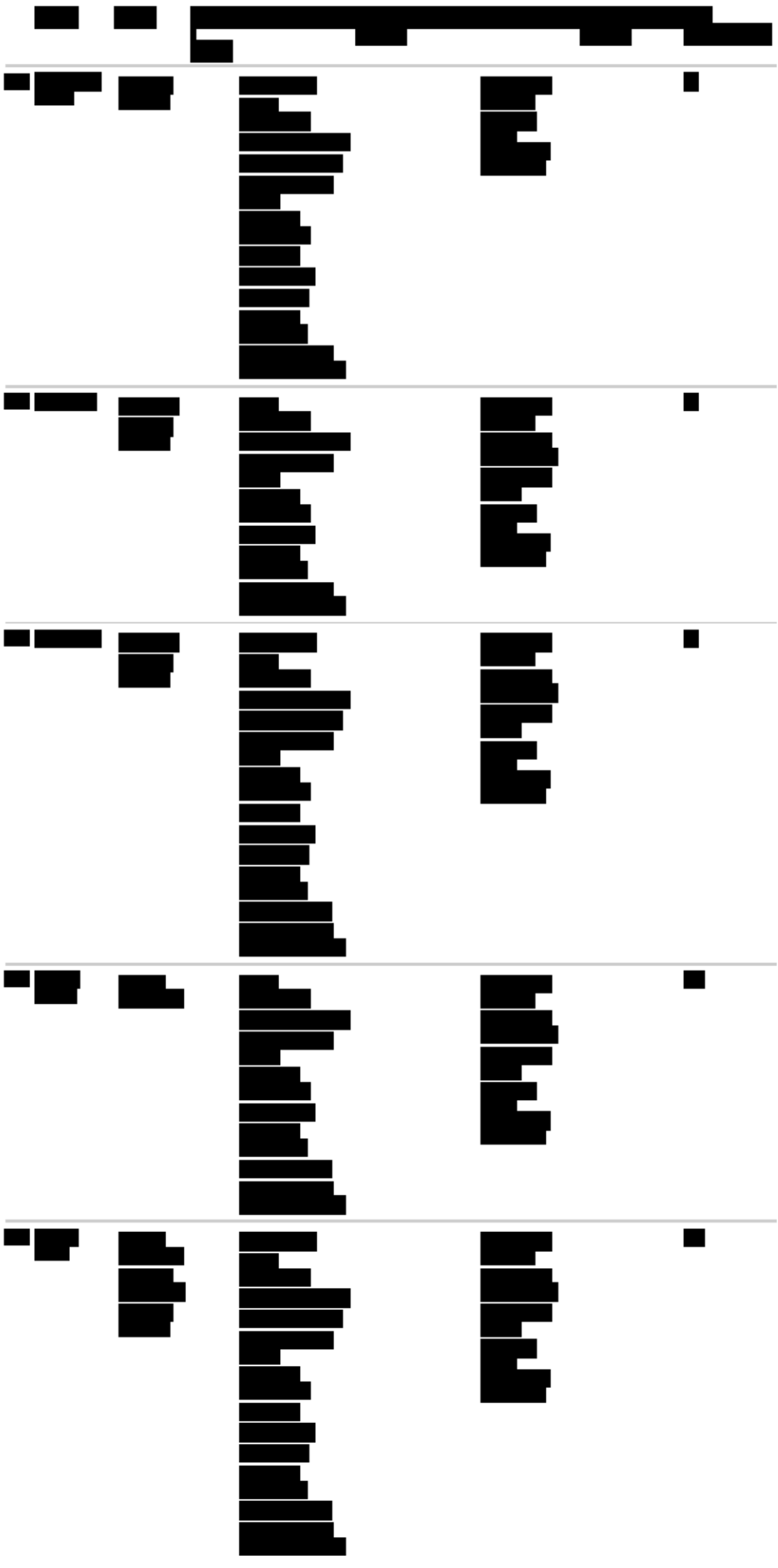
4. * **Is this study supported by the Department of Defense (DoD):**
   - ○ Yes
   - ◉ **No**

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

- None of the above

ID: HM20007902 View: SF - Personnel

[redacted]



[redacted]

ID: HM20007902 View: SF - Conflict of Interest

Conflict of Interest

1. * To the best of your knowledge, do you (as PI) or any other engaged individual hold a financial conflict of interest related to this study?
   - ○ Yes
   - ◉ No

2. If Yes, provide:

- **Name(s) of the engaged conflicted individual(s)**
- **Brief description of the financial conflict of interests**

3. * **Describe any potential non-financial conflicts of interest for members of the research team that could impact the conduct of the study (If None, please state "None"):**
None

4. **Describe any institutional conflict of interest with this research that you or any member of the research team may be aware of:**

ID: HM20007902 View: SF - Communication Plan for Research Team

[redacted]

ID: HM20007902 View: SF - IRB Panel Setup

IRB Panel Setup

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

- (●) **VCU IRB**
- ( ) Western IRB
- ( ) NCI Central IRB
- ( ) Other IRB (Request to Defer to Another Institution)

ID: HM20007902 View: SF - Review Setup

Review Setup

1. * **Does this study involve greater than minimal risk:**
( ) Yes (●) **No**

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

- (●) **Full Board**
- ( ) Expedited
- ( ) Exempt

ID: HM20007902 View: SF - Research Description

Research Description

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
Primary hypothesis:
The hypothesis of this prospective single blind randomized trial is that general anesthesia with laryngeal mark airway is non-inferior in length of procedure to endotracheal tube for patients undergoing ablation for atrial fibrillation.

Secondary hypothesis:
The secondary hypothesis is that general anesthesia with LMA is superior or non-inferior to endotracheal tube in duration of fluoroscopy, post procedure side effects, patient satisfaction and recurrence of PAF.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Study goal is to determine if the use of laryngeal mask airways in ablation of atrial fibrillation is non-inferior to endotracheal tube in terms of procedure length.

3. * **Describe the study's background and significance, including citations, or upload a citation list in document upload. Use lay language whenever possible.**
In recent years it has been shown that catheter ablation of symptomatic atrial fibrillation (PAF) is superior to antiarrhythmic drug therapy with regards to effectiveness and clinical outcomes.1 Atrial fibrillation is the most common cardiac arrhythmia, with high rates of concomitant heart failure, stroke and mortality.2,3 During an ablation procedure, a patient can be managed with intravenous sedation or General Anesthesia. Within this setting, General anesthesia is associated with improved procedure time and cure rate compared to sedation.4

Airway management during GA can be achieved through a LMA or an ETT. The use of LMA compared to ETT has been shown in different surgical populations to decrease procedure and recovery time, improve hemodynamic stability and reduce anesthetic requirements.5,6,7 It has also shown to decrease airway complications, and postoperative nausea/vomiting which are important factors that affect overall patient satisfaction.8,9,10,11,12

Although general anesthesia in electrophysiology procedures is associated with a higher cure rate, there have been reports of increased airway trauma.13 Additionally, it is believed that volatile anesthetics may be associated with increased ventricular action potential duration as well as prolonged QT interval.14,15 The increased usage of opioids during general anesthesia is also thought to interfere with electrophysiology studies by affecting vagal tone.16

At VCU Health system, Anesthesiologists have been successfully using LMA (General Anesthesia) for ablation in PAF in eligible patients for over five years. The investigators are proposing a randomized, single blind study to evaluate the use of LMA versus ETT in this patient population. A concurrent retrospective study will be conducted to evaluate the last two years data of outcomes in this patient population at VCU. The investigators wish to do a prospective study to reduce bias, as the patients who have greater comorbidities are more likely to have ETT for anesthesia, and we believe this will skew the retrospective data when it is collected. The LMA used at VCU Health are LMA Supreme (Teleflex Medicals, Ireland). The study is designed as a non-inferiority study with a primary outcome of procedure length.

Secondary outcomes will include flouroscopy duration, total anesthesia time, total intra- and post- procedure opioids and ionotropes/pressors/chronotropes, patient satisfaction, PAF recurrence.

4. * **Briefly describe the study design, including all interventions or interactions with research participants and access to identifiable data. Use lay language whenever possible.**
Study Design:

This will be a prospective, randomized single blind study comparing the use of general anesthesia with endotracheal tube versus laryngeal mask airway in patients undergoing ablation for paroxysmal atrial fibrillation. Patients will be consented the morning of the procedure and will be conducted only by study personnel. All patient identifiers will be stored in a separate, password protected document from data set. Patients will be randomized, data collected and stored in the secure REDCAP database. REDCap database randomization software will be used to randomize patients into one of the two study groups. Patients will be randomized after they sign informed consent the morning of the procedure. Randomization will be done by study personnel using REDCap and verbally conveyed to anesthesia provider that morning of procedure. The minimum necessary study personnel will have access to patient identifiers.

Power analysis: Estimated mean procedure time 3 hours, range 1.5-4.5 hours, standard deviation 0.9, n = 82 to detect 0.5 hour margin of non-inferiority between the two groups. Including 5% drop-outs, final n=87. Goal enrollment 44 patients per group.

Patients assigned to the ETT tube group will have ETT placed in the safest manner deemed appropriate by attending anesthesiologist. Possible ways to have ETT placed will be using direct laryngoscopy, glidescope or fiberotic intubations. Size of ETT will be decided based on patient charecteristics and discretion of attending anesthesiologist. Once placed, auscultation and capnography will be used to ensure correct placement of ETT.

Patients assigned to the LMA gropu will have LMA placed in a standard fashion by anesthesia provider. LMA size will be decided based on patient charecteristics and at the discretion of attending anesthesiologist. LMA used will be LMA Supreme (Teleflex Medicals, Ireland). Once placed auscultation will be used to ensure correct placement of LMA.

Once assigned to a trial group patients will undergo anesthesia per standard of care, using the necessary anesthestic medications to provide adequate anesthesia, amnesia and analgesia. No change in medications will be dictated by patient enrollment in study.

5. **Upload any supporting tables or documents:**

ID: HM20007902 View: SF - Study Activities

Study Activities

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

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

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

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

ID: HM20007902 View: SF - Bio-Med Project Details

Bio-Med Project Details

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

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

ID: HM20007902 View: SF - Social/Behavioral Project Details

Social/Behavioral Project Details

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

- [x] **Analysis of Information Originally Collected for Non-Research Purposes**
- [ ] Analysis of Data Originally Collected for a Previous Research Study

- [ ] Behavioral Intervention or Experimentation
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] Population Based Field Study
- [ ] Psychophysiological Testing
- [ ] Deception
- [ ] Oral History
- [ ] Interview/Focus Groups
- [x] **Surveys/Questionnaires/Psychometric Testing**
- [ ] None of the Above

2. * **Will any portion of the research be potentially upsetting to the participants:**
   - ( ) Yes
   - (•) **No**

3. **If Yes, describe the nature of the questions and how you will manage the situation should participants become upset:**

4. **Upload ALL instruments/guides that will be used, including scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc.:**

ID: HM20007902 View: SF - Data Collection Details

Data Collection Details

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

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

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

- [x] **Names**
- [ ] Geographic Locators Below State Level
- [ ] Social Security Numbers
- [x] **Dates (year alone is not an identifier)**
- [ ] Ages >89
- [ ] Phone Numbers
- [ ] Facsimile Numbers
- [ ] 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#

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

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

- (•) Yes
- ( ) No

5. **If yes above, describe how participants will be able to withdraw their data:**
Patients will be given a copy of consent form with contact information of study PI's and will be able to withdraw after discharge from the hospital by contacting those individuals. During hospital stay the care teams will have contact information for study personnel in case a patient wishes to withdraw during their hospitalization.

ID: HM20007902 View: SF - HIPAA

HIPAA

1. * **Describe the protected health information that will be obtained or used in this research:**
Data collection:

Demographics: age, race, comorbidities (diabetes, hypertension, coronary artery disease), weight, and height

Procedure time: Will be measured as time from start of procedure to end of procedure, as recorded in minutes

Fluoroscopy time: As measured and reported by electrophysiology and radiology notes, recorded in minutes

Total anesthesia time: Total anesthesia time as measured in minutes and recorded in the anesthesia record, from anesthesia start time to anesthesia stop time

Time to discharge from PACU: time from arrival to PACU until discharge from anesthesia care

Total intra-procedure opioids: Measured in total amount of opioids required during procedure, if different opioids used will convert to oral morphine equivalents

Anesthetic Requirements: average end tidal volatile anesthetics, average amount of intravenous anesthetics

Intraoperative hemodynamics: average heart rate, maximum heart rate, minimum heart rate, average MAP, minimum systolic blood pressure, maximum systolic heart rate, minimum diastolic blood pressure, maximum diastolic blood pressure

Intraprocedure pressor/ionotrope/chronotrope requirements: total measured amounts of all pressors/ionotropes and chronotropes administered intraoperatively

Electrophysiology Parameters: size of left atrium (mm), left ventricular ejection fraction; duration of paroxysmal atrial fibrillation prior to procedure

Airway trauma: Any noted trauma in the anesthesia or post-procedure notes, including damage to lips/teeth, laryngospasm, need for reintubation post procedure

Post-procedure nausea: Measured by number of doses of antiemetics given in the post-procedure time period.

Post-procedure emesis: Measured by number of times patient has emesis during post-procedure time period.

Atrial fibrillation recurrence: defined as recurrence of paroxysmal atrial fibrillation recurring at any time after 6 weeks past the day of procedure. As standard of care these patients are followed up with Holter monitoring for a period of 6 months. Holter monitoring will be done for 48 hour time periods immediately post-procedure, 2 weeks, 6 weeks, 4 months and 6 months post procedure as is standard of care.

Aspiration events: aspiration events as noted in the anesthesia, PACU and post procedure notes would be documented.

Patient Satisfaction: patients will be given an survey by study personnel prior to discharge from the hospital; survey will be conducted in person by study personnel

Cost Analysis: an analysis of cost to patient as well as overall hospital costs will be conducted

2. * **Describe the source(s) of the protected health information:**
Information will be collected both by reviewing data from the medical record of VCU Health, Cerner as well as by in person surveys conducted prior to hospital discharge.

3. * **Explain how the PHI collected or used in this research is the minimum necessary to accomplish this research:**
PHI collected is minimum necessary to determine our primary and secondary outcomes in determining if the use of LMA is non-inferior to ETT for ablation for atrial fibrillation.

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

- [ ] De-identified Data
- [ ] Limited Data Set
- [ ] Waiver of Authorization
- [x] **Partial Waiver of Authorization**
- [x] **Signed Authorization Combined with Consent Form**
- [ ] Signed Authorization as Stand-Alone Form

ID: HM20007902 View: SF - Partial Waiver of Authorization

Partial Waiver of Authorization

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

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

2. **If you selected "Waive some elements of authorization" above, list the elements you want to waive and explain why:**

3. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:**
Partial waiver poses no greater than minimal risk as the patient chart will be briefly reviewed to determine eligibility for study enrollment. No identifiable patient information will be collected or stored prior to patient consent to enrollment in study. Only the minimal necessary study personnel will be involved with identifying possible participants to recruit for study.

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

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

5. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
No other people will have access to the protected health information.

6. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
The partial waiver is necessary for study personnel to identify possible patients for recruitment into the study. Once a patient is deemed not a eligible participant or declines to consent to participate, they will have no identifiable information stored.

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

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

- (•) **Yes**
- ( ) No

ID: HM20007902 View: SF - Existing Data/Specimen Details

Existing Data/Specimen Details

1. * **Describe the source and nature of the data/specimens being obtained:**
Patient information will be collected from existing medical record will include: diagnosis list, comorbid conditions, previous laboratory data, demographics, weight, height.

2. * **Describe how you have access to the data/specimens:**
Access is through VCU Health medical record, Cerner.

3. *

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

Medical record number, dates, and names (as signed on consent forms)

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

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

ID: HM20007902 View: SF - Data Confidentiality and Storage

Data Confidentiality and Storage

1. * **Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. Describe all of the precautions that will be used to maintain the confidentiality of identifiable information, samples or specimens:**
All confidential information will be stored in a password protected manner and only be accessible by the minimum necessary personnel for study completion. All patient information will be stored separately from the patient identifiers, in separate files which will only be accessible by the PI, Co-PIs and other minimum necessary study personnel. Downloaded files will be stored on password protected secure network drives. Data collect and randomization will be done using the secure REDCap databae.

Paper documents will be stored in a locked cabinet in Dr. Prsannas office once they are collected and signed.

2. * **Who will have access to study data:**
PI, Co-PI, research assistant and other study personnel will have access to study data. The fewest necessary personnel will have access to identifiable patient information. Other personnel will only have access to de-identified patient data.

3. * **If applicable, describe the process for assigning codes to the data including :**
- how codes will be assigned
- whether there will be a key linking identifiable information to the data
- where the key will be stored
- who will have access to the key
- when the key will be destroyed
The code will be done in a numeric fashion, as assigned by REDCAP. All patient data and information will be kept exclusively in REDCAP and key only accessible to minimum necessary study personnel. Key will be destroyed once all data collection and analysis are complete.

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

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

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

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

- (•) **Stored indefinitely with identifiers removed**

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

7. If Other, explain:

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

ID: HM20007902 View: SF - Types of Sites

Types of Sites

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

- ◉ **Not Multicenter Study**
- ○ Multicenter Study - VCU Lead
- ○ Multicenter Study - Non-VCU Lead

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

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

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

ID: HM20007902 View: SF - VCU Site Details

VCU Site Details

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

- ☐ Clinical Research Services Unit (CRSU)
- ☐ Massey Cancer Center
- ☑ **VCU Health System**
- ☐ VCU Qatar
- ☐ Other VCU Site

2. * Provide details regarding each VCU Site including:
- what clinics / facilities will be used
- resources that are available for the conduct of this study:
The initial contact and intervention will be at VCU Health electrophysiology unit in the gateway building. Patient contact for survey will be done at the inpatient unit of VCU Health prior to discharge. Patients will have follow-up visits in the clinics of VCU Health Electrophysiology Department.

ID: HM20007902 View: SF - VCU Health System

VCU Health System

1. * The PI has reviewed and agrees to comply with the Conduct of Clinical Research in VCU Health System Patient Care Areas policy:
- ◉ **Yes**
- ○ No

2. * Explain how you will notify and obtain support from patient care providers in the units where the study will be conducted:
Patient care providers, specifically anesthesia pre-op, intra-op and post-op staff, will be informed of the study plan prior to patient enrollment. No change in practice will be required except for anesthesia providers, who will be informed of randomization of patients to LMA vs. ETT.

ID: HM20007902 View: SF - Study Funding

Study Funding

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

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

ID: HM20007902 View: SF - Study Population

Study Population

1. * **Provide the total number of participants you expect to enroll in this study under the VCU IRB:**
   88

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

3. * **Provide justification for the sample size:**
   Power analysis: Estimated mean procedure time 3 hours, range 1.5-4.5 hours, standard deviation 0.9, n = 82 to detect 0.5 hour margin of non-inferiority between the two groups. Including 5% drop-outs, final n=87. Goal enrollment 44 patients per group

4. * **List the study inclusion criteria:**
   - Patients undergoing primary ablation for paroxysmal atrial fibrillation
   - Able to obtain consent in English language
   - BMI <35

5. * **List the study exclusion criteria:**
   - Patients <18 years old
   - Patients undergoing ablation for arrhythmias other than paroxysmal atrial fibrillation
   - American Society of Anesthesiologist physical status of 4 or greater
   - Patients undergoing repeat ablation
   - BMI >35
   - Pregnancy
   - Prisoners
   - Patients unable to give their own consent
   - Patients having trans esophageal echo on the same day
   - Patients unable to give consent in English language
   - Patients will also be excluded if the attending anesthesiologist determines that they would not be suitable candidates for intubation with either method (ETT tube or LMA mask).
   - Patients with severed gastroesophageal reflux disease
   - Patients with high risk of aspiration

6. * **Check all participant groups that are likely to be involved in this study. If it is possible that a regulated vulnerable population (children, pregnant women, prisoners) COULD BE involved in the study, be sure to check them:**

- [ ] Healthy Volunteers
- [ ] Children
- [ ] Emancipated Minors
- [ ] Pregnant Women
- [ ] Fetuses, Neonates, Fetal Material or In-Vitro Fertilization
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] When cancer is integral to the research - cancer Patients, Family Members, Healthcare Providers or Prevention
- [x] **VCU Health System Patients**
- [ ] Non-VCU Patients
- [ ] VCU/VCUHS Students or Trainees
- [ ] VCU/VCUHS Employees
- [ ] Individuals with Limited English Proficiency
- [ ] Active Military Personnel
- [ ] When researching in a K-12 environment - populations Within School Districts or Other Learning Environments

7. **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:**
   Patients who are unable to consent in english language are being excluded as the investigators feel that it would be difficult to uniformly obtain informed consent and collect dta in this patint population.

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

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

Potential Subject Identification and Recruitment

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

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

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

2. If Other, please describe:

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

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

4. If Other, please describe:

5. * Describe specific details for identifying and recruiting participants, including but not limited to:
- Specific locations where recruitment materials will be displayed
- How contact information is obtained for any direct contact with potential participants
- Who will approach and/or respond to potential participants:
No recruitment materials will be displayed. Direct contact will be done in the pre-procedure area of electrophysiology at VCU Health. Study personnel as listed will approach potential participants who have been determined to be eligible for participation in study. Contact information will be from electrophysiology schedule and pre-screening of potential study participants.

Patient screening will be done by evaluating the posted schedule for electrohysiology for each day and potential patients undergoing ablation for atrial fibrillation will be identified. These charts will then be evaluated to determine if they qualify given the studies strict inclusion/exclusion criteria.

6. Describe any special recruitment procedures for vulnerable populations:

7. Upload all recruitment materials including ads, flyers, scripts, letters, email invitations, TelegRAM announcements, and postcard reminders:

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

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

ID: HM20007902 View: SF - Privacy

Privacy

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

Describe how participants' privacy will be protected during:
- identification,
- recruitment,
- screening,
- the consent process,
- conduct of the study, and
- data dissemination:

Patients' privacy will be respected by ensuring that only those people they are comfortable being present will be there during the consent process, and that their participation in the study will not be made known to anyone not providing direct patient care. Patient consent process will occur in area separated by curtains or a door to ensure privacy. Additionally, their records will be accessed by on the minimum necessary number of people for study completion.

ID: HM20007902 View: SF - 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
- [x] **Study related procedures that would be done under standard of care**
- [ ] Study related procedures not associated with standard of care
- [ ] Administration of drugs / devices
- [ ] Study drugs or devices

☐ Other

2. **If Other, explain:**

3. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
No additional financial costs to participants above standard of care will be charged.

4. **If applicable, upload a Cost Analysis form here:**

ID: HM20007902 View: SF - Standard of Care Vs. Research Costs

Standard of Care Vs. Research Costs

1. * **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:**
All associated procedures involving anesthesia, ablation, hospitalization, post procedure holter monitors and post procedure office visits are considered standard of care and will be charged to participant and their insurance.

2. * **Describe the process to determine whether participants' insurance will cover the expenses:**
Patients will have the procedure and all associated expenses submitted to insurance as standard of care.

ID: HM20007902 View: SF - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
- items such as parking/transportation
- total monetary amount
- type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)
- how it will be disbursed:
No compensation.

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

ID: HM20007902 View: SF - Risks, Discomforts, Potential Harms and Benefits

Risks, Discomforts, Potential Harms and Benefits

1. * **Describe the risks to participants associated with this study:**
- physical, psychological, social, legal, financial, and other risks
- seriousness of given risks
- probability or likelihood of given risks
The risks of LMA airway management in atrial fibrillation ablation are: gastric aspiration, intraoral trauma, intraoral nerve paisles, largynospasm, incorrect placement, need for conversion to ETT, sore throat, pulmonary edema, bronchoconstriction

The risks of ETT airway management in atrial fibrillation ablation are: oral injury, dental injury, incorrect placement, hoarseness, sore throat, laryngospasm, laryngeal injury, difficulty swallowing.

There is a potential risk of loss of confidentiality.

2. * **Describe how the risks / harms will be minimized:**
Risks/harms will be minimized as patient data will be carefully managed and accessible by minimum necessary study personnel. Risks are minimized as both groups will have anesthetic plans that have been proven safe and standard of care in a wide variety of clinical situations.

3. **If the disclosure of any of the information obtained during the study would place the individual at risk for harm (legal, reputation, emotional etc.) and the information will be recorded so that the individual could be identified, explain the protections that will be put in place to decrease the risk of disclosure:**

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

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

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

7. * **Describe any potential risks or harms to a community or a specific population based on study findings:**
There is minimal to no risk or harms to a community or specific population based on study findings.

8. * **Describe criteria for withdrawing an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
Participants will be withdrawn from the study if they are converted from their initial randomization. They will also be withdrawn if they request to be removed from study. Patients who do not complete all the post discharge holter monitor evaluations will be kept in the study, and the missed data fields will not be evaluated for that specific patients.

9. * **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns:**
No specified criteria for stopping or changing study protocol for safety concerns.

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

11. * **Describe any potential for direct benefits to participants in this study:**
Participants in this study have potential for benefits of possibly fewer side effects, while also having a similar outcome with regards to procedure length.

12. * **Describe the scientific benefit or importance of the knowledge to be gained:**
The scientific benefit of knowing if the use of LMA is associated with similar (non-inferior) outcome in term of procedure length and determining if the side effects and patient satisfaction are superior could improve the anesthetic care of patients undergoing ablation of atrial fibrillation.

13. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**

14. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all Full Review studies]**

- [ ] DSMB Review Required
- [x] **DSMP Required**
- [ ] Not Required

ID: HM20007902 View: SF - DSMP Details

DSMP Details

1. * **Describe your Data Safety Monitoring Plan for monitoring the data collected to ensure the safety of participants:**
Data collection will be done in a timely manner, with initial data input within a week of each visit. After the first 25 patients are enrolled an interim analysis of primary outcomes as well as adverse outcomes will be done to determine if there is an association between either group and increased incidence of adverse outcomes. If an association is seen the IRB will be notified and the project design reevaluated.

ID: HM20007902 View: SF - Consent Qualifiers

Consent Qualifiers

1. * **Are you submitting your study as exempt and therefore no consent is required:**
   - ( ) Yes
   - (•) **No**

ID: HM20007902 View: SF - Consent Groups

Consent Groups

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

Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Status Change
Qualified Patients	Written/Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant Trainee/Student		Consent will be obtained in the preoperative holding area prior to procedure. Consent will be obtained prior to patient receiving any medications which would potentially interfere with decision making ability.	Patients will be approached by study personnel and given facts of study, no coercion will be utilized to encourage patients to participate.	Patients will be given from time approached by study personnel until medications which may alter decision making ability are given. Approximately 30 minutes to 1 hour prior to procedure start.	
Patient Screening	None of the Above (select waiver below)	Waiver of Some or All Elements of Consent	Principal Investigator Co/Sub-Investigator Research Coordinator Trainee/Student		No consent will be obtained	No consent will be obtained	No consent will be obatined	

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

ID: HM20007902 View: SF - Waiver of Some or All Elements of Consent

Waiver of Some or All Elements of Consent

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

Group	Roles - Other	Consent	Coercion	Decision	Status Change
Patient Screening		No consent will be obtained	No consent will be obtained	No consent will be obatined	

The basic elements of informed consent are as follows:

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

1. * **Describe which of the elements of informed consent you are waiving or altering for <u>each group</u> listed at the top of this page:**
All elements of consent will be waived for this group. This group will consist of the individuals listed on the electrophysiology procedure schedule whose charts will be reviewed for possible eligibility for study recruitment. These patients charts will be accessed by the minimum necessary study personnel. The waiver is requested so appropriate screening can be done without undue burden on patients or study personnel.

2. * **Will you be waiving parental permission for any of the consent groups at the top of this page:**
   - ○ Yes
   - ◉ **No**

3. * **Is this study sanctioned by State and Local Government and designed to study public benefit or service programs:**
   - ○ Yes
   - ◉ **No**

ID: HM20007902 View: SF - Waiver [45 CFR 46.116d] - Adults

Waiver [45 CFR 46.116d] - Adults

1. * **Explain how the research involves no more than minimal risk to the participants:**
   This portion of the research involved no more than minimal risk as this portion will involve screening of potential patients for possible recruitment. The minimum necessary study personnel will evaluate patients chart for eligibility. No change in patient care will occur.

2. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants:**
   Participants rights or welfare will not be affected as there will be no change in patient care secondary to the screening, and the screening will be done by only study personnel and the minimum necessary chart evaluation will be done.

3. * **Explain how the research could not practicably be carried out without the waiver or alteration:**
   Waiver is requested so that patients can be properly screened for possible inclusion into research study. Without screening patients the study personnel would not be able to properly evaluated and enroll potential participants.

4. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not:**
   Patients will not be provided additional pertinent information, as this will be a simple chart review for eligibility for the study.

ID: HM20007902 View: SF - Documents

[redacted]

ID: HM20007902 View: SF - Protocol Complete

[redacted]