Study Identification

1. * **Select the Principal Investigator:**
   Elizabeth Bortell

2. * **Study Title:**
   The Effect of Local Anesthesia when used in Dental Restorative Cases Under General Anesthesia on Postoperative Comfort

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - (●) **Yes**
   - ( ) No

   If this project involves more than one student / trainee investigator, identify the primary contact here and list all student / trainee investigators in the Personnel section. Also ensure all are listed as protocol editors if they need to be copied on IRB correspondence and have authority to make edits.

4. * **Student/Trainee Investigator:**
   Elizabeth Kleefisch

5. * **Please select the primary department or center that this study is being conducted under:**
   Pediatric Dentistry

6. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI

There are no items to display

7. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Carrico	Caroline	ckcarrico@vcu.edu	8048288328	
Kleefisch	Elizabeth	kleefisches@vcu.edu		

8. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - (●) **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ( ) Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ( ) Humanitarian Use of Device for Treatment or Diagnosis
   - ( ) Humanitarian Use of Device for Clinical Investigation

- ○ Emergency Use of Investigational Drug, Biologic or Device
- ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- ○ Center or Institute Administrative Grant Review
- ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

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:

- [x] **Drug**
- [ ] Medical Device
- [ ] Biologic
- [ ] Dietary Supplement
- [ ] Food/Food Additive
- [ ] Color Additive
- [ ] Electronic Products for Human Use (radiation producing)
- [ ] Tobacco Product
- [ ] 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
- [x] **None of the above**

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**

HM20018316 - Elizabeth Bortell
The Effect of Local Anesthesia when used in Dental Restorative Cases Under General Anesthesia on Postoperative Comfort

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 with or without 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

6. * **Is this study initiated by a VCU investigator or a sponsor:**
   - (●) **VCU Investigator initiated**
   - ( ) Sponsor or industry initiated

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
Scientific benefit
Educational benefit for student/trainee investigators leading their own study

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

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

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

7. For Expedited Studies:

Category 1	Clinical Study of Drugs or Devices	Is a clinical study of A) drugs that do not require an IND or B) devices where an IDE is not required or the device is being used for an approved use.
Category 5	Nonresearch Data Collection	Involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes including medical treatment or diagnosis.
Category 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Initial Setup Complete

Protocol Progress:
● **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

HM20018316 - Elizabeth Bortell

The Effect of Local Anesthesia when used in Dental Restorative Cases Under General Anesthesia on Postoperative Comfort

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.**

General Anesthesia is an accepted Advanced Behavior Management Technique approved by the AAPD used to accomplish extensive dental work in young and pre- cooperative children. The use of General Anesthesia in Dentistry is advantageous because it provides – immobility, amnesia, sedation, and analgesia. Due to these effects children are able to undergo extensive dental work in a single sitting with relative ease and little memory of the event (American Academy of Pediatric Dentistry, 2004)

Despite the extensive use of General Anesthesia in Pediatric Dentistry no definitive guidelines exist for the use of local anesthetic in these procedures. AAPD guidelines merely note that local anesthesia has been reported to reduce pain in the postoperative period with marginal evidence(American Academy of Pediatric Dentistry, 2004). To date there have been very mixed results as to the use of local anesthetic in General Anesthesia cases and usage varies. In The Use of Local Anesthesia During Dental Rehabilitations: A Survey of AAPD Members it was shown that 51% of dentists administer local anesthesia less then half of the time during General Anesthesia cases, 76% administered before treatment when used, and 89% via local infiltration when used. It was also shown that Dentists and Pediatric Dentists who completed residency training used less LA during GA cases. Last, they also showed that 21% never use LA during GA cases and 8% always use LA during GA cases (Townsend, Martin, Hagan, & Needleman, n.d.). In Usage of Local Anesthesia During Dental Rehabilitation With General Anesthesia: A Survey of Dental Anesthesiologists it was found that 90% of dentist anesthesiologists prefer local anesthesia at least some of the time and 40% prefer LA use with very rare exceptions (Townsend, Hagan, & Smiley, 2014). From these studies we can see that LA usage for dental cases under General Anesthesia varies greatly and rationale is based on varying limited evidence.
In the literature, there are varying studies as to the effectiveness of LA intraoperatively in controlling post-operative pain in GA dental cases. In Morbidity following dental treatment of children under intubation general anesthesia in a day-stay unit, it was seen that children who were given LA during GA were more likely to experience postoperative dizziness following LA. (Atan et al., 2004)The Effect of Local Anesthetic on Quality of Recovery Characteristics Following Dental Rehabilitation Under General Anesthesia in Children showed no difference for need of postoperative pain medication between those groups that received LA and those that did not. Additionally, in this study they found that 20% of children treated under GA perceived postoperative discomfort due to the sensation of numbness. (Townsend, Ganzberg, & Thikkurissy, 2009)In Perioperative local anesthetic in young pediatric patients undergoing dental extractions under outpatient ‘short-case’ general anesthesia it was noted pain/discomfort and anxiety were not significantly different between the groups that received LA perioperatively under GA and those that did not (Leong, Roberts, & Ashley, 2007)This result was also observed in Local Anesthesia Effects on Postoperative Pain after Pediatric Oral Rehabilitation Under General Anesthesia where post-operative pain in patients undergoing GA was measured with the UPAT scale and found no statistically significant difference in post-operative pain between the two groups(Moness Ali & Hammuda, 2019).

In Local Anesthesia Affects Physiological Parameters and Reduces Anesthesiologist Intervention in Children Undergoing General Anesthesia for Dental Rehabilitation a statistically significant difference was seen in end tidal CO_2 in the cases where dental extractions were performed. It was found that usage of LA in these cases showed better stability of $EtCO_2$. No statistically significance was found in observed respiratory rate and heart rate(Watts, Thikkurissy, Smiley, McTigue, & Smith, n.d.). Very limited research is available on this subject and more research is needed to confirm the validity of the results of this study.

American Academy of Pediatric Dentistry. (2004). Clinical guideline on the elective use of minimal, moderate, and deep sedation and general anesthesia for pediatric dental patients. Pediatric Dentistry, 26(7 Suppl), 95–103. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15656444
Atan, S., Ashley, P., Gilthorpe, M. S., Scheer, B., Mason, C., & Roberts, G. (2004). Morbidity following dental treatment of children under intubation general anaesthesia in a day-stay unit. International Journal of Paediatric Dentistry, 14(1), 9–16. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/14706023
Leong, K. J., Roberts, G. J., & Ashley, P. F. (2007). Perioperative local anaesthetic in young paediatric patients undergoing extractions under outpatient “short-case” general anaesthesia. A double-blind randomised controlled trial. British Dental Journal, 203(6), E11; discussion 334-5. https://doi.org/10.1038/bdj.2007.724
Moness Ali, A. M., & Hammuda, A. A. (2019). Local Anesthesia Effects on Postoperative Pain After Pediatric Oral Rehabilitation Under General Anesthesia. Pediatric Dentistry, 41(3), 181–185. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/31171068
Townsend, J. A., Ganzberg, S., & Thikkurissy, S. (2009). The effect of local anesthetic on quality of recovery characteristics following dental rehabilitation under general anesthesia in children. Anesthesia Progress, 56(4), 115–122. https://doi.org/10.2344/0003-3006-56.4.115
Townsend, J. A., Hagan, J. L., & Smiley, M. (2014). Use of local anesthesia during dental rehabilitation with general anesthesia: A survey of dentist anesthesiologists. Anesthesia Progress, 61(1), 11–17. https://doi.org/10.2344/0003-3006-61.1.11
Townsend, J. A., Martin, A., Hagan, J. L., & Needleman, H. (n.d.). The use of local anesthesia during dental

rehabilitations: a survey of AAPD members. Pediatric Dentistry, 35(5), 422–425. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24290554
Watts, A. K., Thikkurissy, S., Smiley, M., McTigue, D. J., & Smith, T. (n.d.). Local anesthesia affects physiologic parameters and reduces anesthesiologist intervention in children undergoing general anesthesia for dental rehabilitation. Pediatric Dentistry, 31(5), 414–419. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/19947137

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
For the purpose of this study, the following questions were addressed:
Does administration of local anesthesia at the end of restorative procedure under general anesthesia result in decreased postoperative pain management in children?

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Current guidelines for local anesthetic use during dental cases under general anesthesia are not specified. In the literature there are mixed reports regarding its use some addressing solely intraoperative effects, or postoperative pain. This study is needed due to the limited numbers of studies in the area and the lack of evidence for definitive guidelines. In particular, in this study, I hope to address the effects of local anesthesia use intraoperatively on postoperative pain control and irritability.

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

The purpose of this study is to determine the effect of local anesthesia on postoperative irritability and pain management in dental cases under general anesthesia. This information is important because currently no guidelines exist to define usage of local anesthetics in dental cases under GA. Current practitioner usage is due to clinical judgement and practice varies widely across the United(Townsend, Martin, Hagan, & Needleman, n.d.). My goal is to provide some answers to whether local anesthesia is beneficial and provide evidence if local anesthesia usage helps control postoperative pain, and ease of recovery in PACU and home or not. This information will be obtained through the use of pain scores pre and post operatively in the hospital, parental behavior questionnaire for postoperative evaluation.

5. * **Describe any potential for direct benefits to participants in this study:**
Local anesthetic usage for dental restorative work under GA varies greatly between providers due to lack of guidelines on the subject. It is anticipated based upon previous research that those patients that do receive local anesthesia will have better post operative recovery and less postoperative distress. Additionally, it is anticipated, based upon the results of previous studies that local anesthesia will provide marginal to no benefit for stability of vital signs for restorative dentistry procedures intraoperatively.

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:**
There are no expected social impacts of this study.

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
View	Kleefisch CV	Kleefisch CV.docx	0.01	10/28/2022 11:45 AM	Elizabeth Kleefisch	CV/Biosketch	Yes
View	Research Presentation Script and Flow Sheet	Research Presentation Flow- FINAL.docx	0.04	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Anesthesia Data Collection as part of Data Collection Packet	Anesthesia flow chart.docx	0.01	7/22/2020 12:04 PM	Kathryn Skarda	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Data collection packet	Research Data Packet .docx	0.01	7/22/2020 12:02 PM	Kathryn Skarda	Research Measure	Yes
View	FDA Lidocaine	Lidocaine - Dental FDA.pdf	0.01	5/13/2020 4:20 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable
View	IND Exemption for Lidocaine	IND Exemption for Lidocaine.docx	0.01	4/17/2020 10:03 AM	Kathryn Skarda	Drug/Device Brochure	Yes
View	Bortell CV	Bortell CV.pdf	0.01	2/18/2020 12:28 PM	Kathryn Skarda	CV/Biosketch	Yes
View	GA Post- Op Instructions	General Anesthesia Post-Op Instructions.docx	0.01	12/17/2019 2:00 PM	Kathryn Skarda	Other	Not Applicable
View	FLACC Behavior Scale	FLACC Behavior Scale.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	Parent's Post Operative Pain Measure	Parents Post Operative Pain Measure.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	MSDS Lidocaine	MSDS.pdf	0.01	12/4/2019 1:14 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable

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.
   60

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   This study will take place at VCU Children's Hospital of Richmond through the Children's Pavillion and Brook Road Sites. The maximum number of anticipated participants between both sites is 60 children.

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   This is the maximum anticipated participants that we believe we will be able to treat within out expected study timeline. We also believe that 60 participants will provide enough data to adequately answer our research questions.

4. * **List the study inclusion criteria:**
   Study will include patients undergoing GA for dental restorative work at VCU Children's Hospital of Richmond Pavillion and Brook Road Centers. Study will include patients under 6 years of age. Children above 6 years of age should be able to generally tolerate dental work in the chair if normally developing, including children older may distort data due to behavior issues.

5. * **List the study exclusion criteria:**
   In this study we will exclude children with any sensory or behavioral issues, as this may greatly distort data gathered. We will exclude patients requiring extractions or surgical procedures as local anesthesia may be more beneficial in these patients for pain and hemostasis control intraoperatively. In addition, we recommend the anesthesiologist not to give post-operative Precedex or Ketorolac as it is not standard of care. Patients given Precedex or Ketolorac post-operatively by the anesthesiologist will be withdrawn from the 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.**

Background, Rationale & Goals Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
For the purpose of this study, the following questions were addressed:
Does administration of local anesthesia at the end of restorative procedure under general anesthesia result in decreased postoperative pain management in children?

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Current guidelines for local anesthetic use during dental cases under general anesthesia are not specified. In the literature there are mixed reports regarding its use some addressing solely intraoperative effects, or postoperative pain. This study is needed due to the limited numbers of studies in the area and the lack of evidence for definitive guidelines. In particular, in this study, I hope to address the effects of local anesthesia use intraoperatively on postoperative pain control and irritability.

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 document
   - [x] **No recruitment materials**

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of 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 VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- 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, approach, 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 will be recruited from patients presenting for or needing full mouth dental rehabilitation. Patients will be recruited by doctors from VCU dental clinic and Brook Rd. Clinic during GA consultation appointment. Patients who could be potential research participants will be given information about the research day of their consultation as well as a consent form to review on their own time. Potential participant information will be collected and enclosed in a Google Doc Sheet on VCU account. This would include just patient date of birth, name, MRN, phone number and surgery date. Patients identified as potential research candidates will be approached day of surgery with the option to participate in

the research. At time of consent DOS patients will be assigned a participant number which will be used to mark record and randomize participants. This participant number will correspond to the initial demographics collected. No additional screening activities will be done as we already have a high volume of consultations coming through our clinics.

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. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
   4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

   See the help text for additional guidance
   This study has been modeled as a double-blinded randomized control trial. Patients will include healthy children (ASA 1 or ASA 2) without any history of behavioral issues under the age of 6 who had been treatment planned to have exclusively; restorative work, prefabricated crowns and space maintainers.
   Dental treatment will be performed under general anesthesia at the Children's Hospital of Richmond Brook Rd. and Children's Pavilion Campuses. Sixty candidates will be recruited from patients presenting for or needing full mouth dental rehabilitation. Patients will be recruited by doctors from VCU Pediatric Dental Clinic and Children's Hospital of Brook Rd. Pediatric Dental Clinic during GA consultation appointments. Participant information will be collected and enclosed in a Google Doc Sheet on Secure VCU Server. Patients will be assigned a participant number which will be used to randomize participants and de-identify patient information. Patients will be randomized into two groups; those that receive LA while under GA and those that will not.
   Day of surgery, patients will be evaluated preoperatively using the FLACC pain/behavior scale by the preoperative nurse who is blinded to the candidates group in the study. Intraoperatively, patients will be given either local anesthetic (2% Lidocaine with 1:100,000 epi) infiltration at six sites (once at each of the 6 sextants, L posterior, anterior, R posterior on each arch) of the mouth by the dental surgeon performing the surgery or no local anesthesia will be utilized. Administration of local anesthetic will be a weight based calculation and will be locally infiltrated 10 minutes prior to the end of the procedure. Postoperatively patients will be evaluated in the Post Anesthesia Care Unit (PACU) by a nurse blinded to the intervention before discharge using the same initial pain/ behavior scale, the FLACC scale, used preoperatively. Patients will then be discharged to home when stable and parents of patients will then be given a standard set of post-operative instructions encompassing instructions for the possibility of anesthetized tissues (see documents). Patient's time in the PACU will be noted upon discharge. Lastly, that evening parents were asked to evaluate their children over the phone using a parent administered post- operative evaluation, the Parent's Post-Operative Pain Measure (PPPM).

7. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which 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.).
   See the help text for additional guidance

   As part of the study patients will be assigned local anesthetic protocol based upon treatment group. Local anesthesia use in dental cases under general anesthesia varies greatly from provider to provider. Ordinarily provider preference would dictate use. No alteration will be made to local anesthesia routine use. Standard infiltration volumes will be used in this study and will be administered based on a weight-based calculation. Location of local anesthetic will be infiltrated in all 6 sextants of the oral cavity. No additional medical tests will be performed as part of the study. As part of the study patients will have a pre- and post operative FLACC score pain assessment. This is a standard pain assessment that is routinely preformed by nursing staff regardless of participation in the study upon patient arrival and before patient departure. Next, throughout the study the patient will be observed by the anesthesiologist throughout the procedure as customary and the anesthesiologist will intervene as customary by deepening the anesthetics if needed. As part of the research patients will be contacted by postoperative phone call which is customary, however as part of this phone call parents will be asked questions to assess patients post operative pain using the parents post operative pain measure tool which is not customary and data will be solely collected for research.

   Study specific activities:
   1. Randomization to LA

2. Recording FLACC score pre/postop, time in PACU
3. Parent/guardian pain measure tool during standard postop phone call

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 patients do not choose to participate in this study they will undergo FMDR under GA with LA as prescribed by the dentist and anesthesiologist providing the case.

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:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
View	Kleefisch CV	Kleefisch CV.docx	0.01	10/28/2022 11:45 AM	Elizabeth Kleefisch	CV/Biosketch	Yes
View	Research Presentation Script and Flow Sheet	Research Presentation Flow- FINAL.docx	0.04	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Anesthesia Data Collection as part of Data Collection Packet	Anesthesia flow chart.docx	0.01	7/22/2020 12:04 PM	Kathryn Skarda	Research Measure	Yes
View	Data collection packet	Research Data Packet .docx	0.01	7/22/2020 12:02 PM	Kathryn Skarda	Research Measure	Yes
View	FDA Lidocaine	Lidocaine - Dental FDA.pdf	0.01	5/13/2020 4:20 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable
View	IND Exemption for Lidocaine	IND Exemption for Lidocaine.docx	0.01	4/17/2020 10:03 AM	Kathryn Skarda	Drug/Device Brochure	Yes
View	Bortell CV	Bortell CV.pdf	0.01	2/18/2020 12:28 PM	Kathryn Skarda	CV/Biosketch	Yes
View	GA Post- Op Instructions	General Anesthesia Post-Op Instructions.docx	0.01	12/17/2019 2:00 PM	Kathryn Skarda	Other	Not Applicable
View	FLACC Behavior Scale	FLACC Behavior Scale.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	Parent's Post Operative Pain Measure	Parents Post Operative Pain Measure.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	MSDS Lidocaine	MSDS.pdf	0.01	12/4/2019 1:14 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable

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Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other "primary" or "initial" activity and that will be used secondarily in the research study.

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)
   - [x] **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)**
   - [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, 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 and methods of data collection that apply to this study (selections will branch):**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [ ] Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)
   - [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [ ] Audio / Video recording or photographing participants
   - [x] **Observations**
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

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

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

Bio-Medical Drug / Biologic / Supplement / Other Compound Details

1. * List all drugs and/or biologics:

	Drug	Manufacturer	Types	FDA Labeling	IND Holder	IND Number
View	2% Lidocaine with 1:100,000 epinephrine	Henry Schein	FDA Approved and being used as approved	Yes	Not Required	IND Exempt

2. * Will the Investigational Drug Service (IDS) pharmacy be utilized:
Not Applicable

3. * A. For each drug/biologic listed above, upload an investigator's drug brochure or package insert/FDA labeling.

B1. For drug products that require an IND, upload at least one of the following for verification of the IND number:
- External sponsor's protocol including IND number and signed Form FDA 1572 for the VCU Principal Investigator
- Communication from the external sponsor verifying the IND number and signed Form FDA 1572 for the VCU Principal Investigator
- VCU sponsor-investigator's FDA IND protocol including IND number
- Communication from the FDA with verification of the IND number

B2. *For drug products that qualify for IND exemption* under under 21 CFR 312.2(b), upload one of the following for each applicable drug:
- A document explaining, with protocol-specific information, how the drug's use in this study meets the relevant criteria for IND exemption under 21 CFR 312.2(b).
- The completed "Determination of IND Exemption for Marketed Drugs" form available on the VCU Faculty-Held IND or IDE website at go.vcu.edu/indide.
- External sponsor's protocol including IND exemption information
- Communication from the external sponsor verifying the IND exemption
- Communication from the FDA with verification of IND exemption

C. If the Investigational Drug Service Pharmacy (IDSP) is not utilized, upload the IDSP management plan approval.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
View	Kleefisch CV	Kleefisch CV.docx	0.01	10/28/2022 11:45 AM	Elizabeth Kleefisch	CV/Biosketch	Yes
View	Research Presentation Script and Flow Sheet	Research Presentation Flow- FINAL.docx	0.04	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Anesthesia Data Collection as part of Data	Anesthesia flow chart.docx	0.01	7/22/2020 12:04 PM	Kathryn Skarda	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Collection Packet						
View	Data collection packet	Research Data Packet .docx	0.01	7/22/2020 12:02 PM	Kathryn Skarda	Research Measure	Yes
View	FDA Lidocaine	Lidocaine - Dental FDA.pdf	0.01	5/13/2020 4:20 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable
View	IND Exemption for Lidocaine	IND Exemption for Lidocaine.docx	0.01	4/17/2020 10:03 AM	Kathryn Skarda	Drug/Device Brochure	Yes
View	Bortell CV	Bortell CV.pdf	0.01	2/18/2020 12:28 PM	Kathryn Skarda	CV/Biosketch	Yes
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View	MSDS Lidocaine	MSDS.pdf	0.01	12/4/2019 1:14 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable

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 collected in a data collection packet. Pre-operatively Nurses in Pre-Op will record FLACC score from the patients chart into the data collection packet. Post- operatively Nurses in Post-op will record FLACC score from the patients chart into the data collection packet. Time in PACU will also be collected.

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.**
   Information collected throughout the study on the data collection form will be de-identified and labeled with participant number. Patient identifiers will be stored on secure VCU google drive including patient name, mrn, date of birth, day of surgery,participant number and patient phone number. Patient data will not be re-identified. Patient identifiers will be used merely to access data from the anesthetic record and dental record.

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

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. * **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.**
   None

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.**
   Cost of Full Mouth Dental Rehabilitation under General Anesthesia with necessary Full Mouth Series Radiographs as standard part of their dental treatment they are scheduled to receive

4. * **Describe the process to determine whether participants' insurance will cover the expenses.**
   Patient insurance will be pre-authorized before scheduling of procedure and before selection for study.

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   4. how you arrived at this amount
   5. What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)

   None

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

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.

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Research Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

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Consent Process

1. * List all consent groups:

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Parent/ Guardian Consent	Signed Parent/Guardian Permission or Legally Authorized Representative Consent Short Form Consent (limited applicability)	No Waivers Requested	Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator		Not using electronic signature platforms	Parents will be initially presented with the option to be considered to participate in the study at the end of their consultation for surgery visit. Parents will be provided with a copy of the consent form on that date. Parents will be asked to sign consent day of surgery preoperatively	Other protection(s) not listed here – describe below	Parents of patients will be asked to participate in the study at the close of their consultation for surgery. Parents of patients will have the time from the date of consultation to the day of surgery to decide if they would like to participate in the study.	

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
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View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
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View	MSDS Lidocaine	MSDS.pdf	0.01	12/4/2019 1:14 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable

Short Form Consent

Consent groups that require a short form consent document:

Groups	Types	Waivers	Roles	Roles Other	Consent	Decision	Status Change
Parent/ Guardian Consent	Signed Parent/Guardian Permission or Legally Authorized Representative Consent Short Form Consent (limited applicability)	No Waivers Requested	Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator		Parents will be initially presented with the option to be considered to participate in the study at the end of their consultation for surgery visit. Parents will be provided with a copy of the consent form on that date. Parents will be asked to sign consent day of surgery preoperatively	Parents of patients will be asked to participate in the study at the close of their consultation for surgery. Parents of patients will have the time from the date of consultation to the day of surgery to decide if they would like to participate in the study.	

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 will only be using a short form consent for those few individuals in the study for whom english is not the primary language and a translator will be utilized for the consent.

Consent Plan Complete

Protocol Progress:
● **INITIAL SETUP**
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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.

   Local anesthesia is routinely used in dental treatment and can lead to short term post operative numbness. In patients that will receive local anesthesia they will have transient numbness that can lead to some discomfort due to the temporary altered sensation in the area. Additionally due to the numb sensation some patients can cause inadvertent self inflicted trauma in the area. Additionally, throughout the course of this study there is a risk of loss of confidentiality thorough lost or shared information. Last, anticipate the risk of survey completion that being asked survey questions may cause distress or anxiety since their child will be evaluated. In addition, as part of a randomized control trial groups will be randomized using block randomization- participants will not be able to choose their protocol once enrolled in the study.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   These risks will be minimized by first, all parents will be provided the same written and verbal post operative instructions including information advising parents that portions of the child's mouth may be numb and they should monitor them closely for the next few hours to ensure of no lip of tongue biting. Second, clinical data stored will be de-identified and stored on a secure VCU server database. Lastly, surveys performed on child will be done through pure objective scale. No questioning will be directed towards child. At home survey will be directed at parents and includes commonly utilized post operative questions to assess how a child is doing after surgery and provide the best post operative guidance (ex. diet, activity, pain management). To minimize the risk of bias block randomization will be utilized and patients will receive post operative instructions encompassing post operative guidance (e.g post operative instructions reviewing local anesthesia will be given to all participants even if it was not utilized.)

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   No potential risks or harms to a specific community anticipated.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   Patient will be monitored by both dentist and anesthesiologist throughout the entirety of the case and monitored by the nurses post operatively. Any medical interventions will be performed by these personnel if necessary. No psychological intervention anticipated.

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.:**
   After a patient has been accepted in the study and consent obtained patients will only be withdrawn if it is determined during comprehensive exam under GA if a patient requires EXT of any teeth. In that case patient will have local anesthesia administered in the area of extraction, extraction will be performed and patient will be withdrawn from the study. Patients given Precedex or Ketolorac post-operatively by the anesthesiologist will be withdrawn from the study. These are given based on anesthesia provider's preference. The protocol will discourage the use of these medications for study participants as it would alter the effects of the intervention.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**

None anticipated. Study is evaluating methods that are currently utilized to evaluate which has better patient response. No safety concerns anticipated as lidocaine 2% with 1:100,000 epi is routinely used by some providers in FMDR under GA.

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

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

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

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

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. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

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.)**
   - [ ] Verifying identity before discussing personal information.
   - [ ] Asking the participant if they are comfortable answering questions in that location
   - [ ] Asking the participant if they are comfortable with having other people present (if any)
   - [ ] Moving away from other people when conducting activities in public spaces or offering a private space
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
   - [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
   - [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
   - [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area

- [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
- [ ] Allowing people to distance themselves from other participants during group activities
- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**

- [ ] Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)
- [ ] Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.
- [ ] Obtaining permission prior to sending text messages
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] Offering a way to save and return later to the online activity if privacy is compromised
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no remote interventions or interactions with participants**

4. * **Protections when mailing study materials to/from participants:**

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

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:

- [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
- [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**

- [ ] 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
- [x] **Only publishing or presenting aggregate results or findings (i.e. no individual-level information)**
- [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe below
- [ ] Other protections not listed in this question – describe below

6. **Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance*.**
   Patients will be identified for the study during routine dental consultation for GA. For the consultation patients will be seen in a dedicated dental cubicle. Each patient will be seen in their own cubicle and this is where all information will be collected and the research will be discussed. No screening or recruitment activities will be performed. All participant demographic information will be collected on a secure VCU google Doc with the patient name and their participant number. All information collected during the study will be collected on a de-identified data collection form Day of Surgery. After collection, data collection forms will be stored in locked storage. Data will be inputed from data collection form and will be stored on secure VCU Google Docs with de-identified information. Informed consent for the study will be obtained day of surgery. Parents will be consented in their child's preoperative room in PACU by the Nurse using a script and research flow sheet. Patients will be assigned a research candidate number and all data collected will be de- identified through use of this number. All data will be initially be collected on a data collection for day of surgery. After surgery data collection form will be placed in locked storage until it is imputed and stored digitally on VCU protected data bases - red cap survey software and google sheets. After data is imputed Data collection sheets will be disposed of at VCU clinic in Secure locked shed container. Data will be accessed by Research members only through secure access to VCU sheets. Only those on research team will have access to view and edit data on sheet and red cap survey software.

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**
   - [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
   - [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no paper research materials

2. * **Protections for research specimens:**
   - [ ] Maintaining control of specimens at all times, including when at an off-campus location
   - [ ] Storing specimens in a secure location accessible only to authorized study personnel
   - [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
   - [ ] Final destruction of specimens will be in accordance with VCU policies and specimen containers 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, multi-site data collection platforms):
     • 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 that are provided to participants for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**
   - [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
   - [ ] Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants
   - [ ] Device/app set up by VCU Information Security
   - [ ] 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 the device/app and protection below
   - [x] **N/A – no computers or devices/apps being provided for participant use outside the lab**

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

6. **Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.**

   See the help text for additional guidance.
   Participant contact information will be stored on VCU secured google sheets with associated research participant number. Research Data will be initially collected Day of Surgery on a Data collection packet. data Collection packet will be collected and scanned and data input on VCU secured google docs identified through date of collection and research participant number. After scanning paper surveys original copies will be shredded. Up until that time data will be stored, de-identified in a folder locked in office desk at VCU Pediatric Dental Clinic. Data collected will be stored digitally on red cap and vcu google sheets associated solely with research participant number. Consents will be kept in folder locked in office dental at VCU Pediatric Dental Clinic. After surgery data
   collection form will be placed in locked storage until it is imputed and stored digitally on VCU protected databases - red cap survey software and google sheets

7. * **If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PI's department for the conduct of this protocol (not for future sharing),**
   1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
   2) give a description of what identifiers and/or codes will accompany the data/specimens.
   If data/specimens are not being sent/released outside of the VCU study team or the PI's department, state that:
   Research data will not be shared with anyone outside of the VCU study team.

8. * **Select all identifiers that will be collected at any time 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 over 89 (age under 89 is not an identifier)
   - [x] **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
- [x] **Other Unique Identifier**
- [ ] No Identifiers
- [ ] Employee V#

9. **If "Other Unique Identifier" was selected above, describe the identifiers:**
   Date of Birth, Patient age- all patients in study ages 6 and under.

10. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names and/or other identifiers 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 there will be no linkage key, state that.

    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.
    Patients will be assigned sequential research participant numbers which will serve as the subject ID # and will de-identify the research data from the participant. A key will be made which will include patient information associated with research participant number. This key will be stored in VCU secured google sheets and will be stored in a separate digital VCU sheet than the data collected. Only those investigators involved in the study will have access to the key. Key will be destroyed at the conclusion of the study after the study has been published.

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] **N/A - study does not require screening procedures**
   - [ ] 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

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. * **If Yes , describe the process (oral, written, email, letter, etc.) that participants should use to request withdrawal of their data/specimens. Identify if there is a timepoint when withdrawal will no longer be an option and/or if the amount of data that can be withdrawn is reduced at different points in the study.**
   Patients can withdraw from the study by orally stating they wish to do so. Patients have the option to withdraw from the study up until patient has left pre-operative area.

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

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

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

   ☐ Will use directly identifiable information or specimens.

   ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies 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. VCU IRB studies 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

☐ *(VCU IRB studies will be asked more questions about this on a later page.)*

☑ **Will not use information/specimens for purposes beyond this study.**

☐ Not sure and will submit an amendment when known

☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share 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. VCU IRB studies 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. VCU IRB studies 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 (VCU IRB studies will be asked more questions about this on a later page.)

- [ ] Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)
- [x] **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**

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Pertinent Results 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**

Risk Benefit Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**

⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

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)

- [x] **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

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Children

1. * **Check all that apply to the study:**

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

2. **If multiple categories are selected above, explain which study groups are covered by each selected category (e.g. treatment vs. control groups):**

3. * **Describe how you plan to obtain permission of parents or legal guardians. If you have indicated this study will fall into categories 406 or 407, please describe here how you will obtain permission from both parents.**
Consent will be obtained by parents day of surgery as part of the written consent day of surgery for dental procedures under GA.

4. * **Describe how children will be assented to participate in the study (i.e. what will the study team do during the assent process to ensure the child understands what the research involves).**
Children included in the study will be under 6 years of age. Due to patient cognitive level at this stage in development assent will not be obtained directly from research participants.

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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, and their qualifications

   For patients initial consultation, patients will be seen in the dental clinic for translation purposes we will utilize either the professionally trained VCU hospital interpreters, MARTI video interpreters or the CyraCom interpreter network phone service. At this initial consultation patients and their parents will be informed of the research study. Protocol and consent will be reviewed with translator assistance. Day of surgery patients will be again approached with the option of participating in the study. For translation day of surgery we will utilize either professionally trained VCU hospital interpreters, MARTI video translation service or the CyraCom interpreter network phone service. It is anticipated that our study will include less than 5% LEP subjects so a short form consent document will be used and included as part of our consent.

2. * **Describe any additional risks or harms to the individual because of their limited English proficiency and how these will be minimized.**
   No additional risks are interpreted because professional medical translation services will be utilized.

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
View	Kleefisch CV	Kleefisch CV.docx	0.01	10/28/2022 11:45 AM	Elizabeth Kleefisch	CV/Biosketch	Yes
View	Research Presentation Script and Flow Sheet	Research Presentation Flow- FINAL.docx	0.04	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Anesthesia Data Collection as part of Data Collection Packet	Anesthesia flow chart.docx	0.01	7/22/2020 12:04 PM	Kathryn Skarda	Research Measure	Yes
View	Data collection packet	Research Data Packet .docx	0.01	7/22/2020 12:02 PM	Kathryn Skarda	Research Measure	Yes
View	FDA Lidocaine	Lidocaine - Dental FDA.pdf	0.01	5/13/2020 4:20 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable
View	IND Exemption for Lidocaine	IND Exemption for Lidocaine.docx	0.01	4/17/2020 10:03 AM	Kathryn Skarda	Drug/Device Brochure	Yes
View	Bortell CV	Bortell CV.pdf	0.01	2/18/2020 12:28 PM	Kathryn Skarda	CV/Biosketch	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	GA Post- Op Instructions	General Anesthesia Post-Op Instructions.docx	0.01	12/17/2019 2:00 PM	Kathryn Skarda	Other	Not Applicable
View	FLACC Behavior Scale	FLACC Behavior Scale.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	Parent's Post Operative Pain Measure	Parents Post Operative Pain Measure.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
View	MSDS Lidocaine	MSDS.pdf	0.01	12/4/2019 1:14 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable

Populations with Special Considerations Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
● **RISKS, PRIVACY & CONFIDENTIALITY**
● **POPULATIONS WITH SPECIAL CONSIDERATIONS**
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

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Study Funding

1. * Have you applied for funding:

- ○ Yes
- ● **No**

2. Is this study already funded:

- ○ Yes
- ● **No**

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - [x] **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
   - [x] **Other VCU Site**

   Non-VCU Site Information

   Non-VCU sites should be selected whenever any of the following situations apply:
   a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
   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
   - [x] **No Non-VCU Sites**

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

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

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

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	Consent 11.29.22 Clean.pdf	0.21	12/1/2022 10:30 AM	Kathryn Skarda	Consent/Assent/Information Sheet	Yes
View	Kleefisch CV	Kleefisch CV.docx	0.01	10/28/2022	Elizabeth	CV/Biosketch	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
				11:45 AM	Kleefisch		
View	Research Presentation Script and Flow Sheet	Research Presentation Flow- FINAL.docx	0.04	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Research Consent Presentation and Flow Sheet	Research Consent Flow Sheet - FINAL.docx	0.03	8/16/2020 6:50 PM	Kathryn Skarda	Research Protocol	Yes
View	Anesthesia Data Collection as part of Data Collection Packet	Anesthesia flow chart.docx	0.01	7/22/2020 12:04 PM	Kathryn Skarda	Research Measure	Yes
View	Data collection packet	Research Data Packet .docx	0.01	7/22/2020 12:02 PM	Kathryn Skarda	Research Measure	Yes
View	FDA Lidocaine	Lidocaine - Dental FDA.pdf	0.01	5/13/2020 4:20 PM	Kathryn Skarda	Drug/Device Brochure	Not Applicable
View	IND Exemption for Lidocaine	IND Exemption for Lidocaine.docx	0.01	4/17/2020 10:03 AM	Kathryn Skarda	Drug/Device Brochure	Yes
View	Bortell CV	Bortell CV.pdf	0.01	2/18/2020 12:28 PM	Kathryn Skarda	CV/Biosketch	Yes
View	GA Post- Op Instructions	General Anesthesia Post-Op Instructions.docx	0.01	12/17/2019 2:00 PM	Kathryn Skarda	Other	Not Applicable
View	FLACC Behavior Scale	FLACC Behavior Scale.docx	0.01	12/17/2019 12:03 PM	Kathryn Skarda	Research Measure	Yes
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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)**
- **FDA Form 1572 investigators, and**
- **Other personnel whose roles 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	Elizabeth Bortell	Principal Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Clinical Services Data Collection - Interviews/Surveys		Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Caroline Carrico	Co/Sub-Investigator		Data Analysis Project Coordination Data Management Data Entry Study Design Data Coding		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Jeannette Kierce	Co/Sub-Investigator		Data Analysis Project		Experience - Research		no

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
			Coordination Data Collection - Direct Observation Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Clinical Services Data Collection - Interviews/Surveys		Experience - Clinical Education and/or Professional Preparation		
View Elizabeth Kleefisch	Lead Student/Trainee Investigator (leading their own project)		Data Collection - Direct Observation Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation Trainee		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:**
Team calibration meeting will take before start of study via zoom meeting software with review of written protocols for study. Throughout study communication will be completed through secure VCU email. Periodic meetings will be completed throughout study for review of data and data analysis minimally once per quarter.

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.**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
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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 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.

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**

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 at https://dms.vcu.edu**.**
   ● **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 submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
   ● **Yes** ○ No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):
   ○ Yes
   ○ No
   ● **N/A - not using external technology**

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

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 or PRMC in this study's topic area. If you do not have PROC or PRMC approval, please visit onetrac.vcu.edu for additional information and to submit your project for review.

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 **https://research.vcu.edu/human-research/regulatory-affairs/**.

Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a copy of your FDA
submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

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 hazardous biological agents ("biohazardous agents") that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

- Any functional recombinant viruses (especially viruses that may integrate into the patients' genome).

- Expression or administration of biological toxins.

- Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

- Introduction or expression of rDNA or synthetic nucleic acids

- Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

- Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)
To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**

○ Yes

● **No**

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

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**

○ Yes

● **No**

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
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HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements

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

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - [x] **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - [x] **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.**
   As part of the study patient anesthesia record, and patient dental record will be reviewed and used in this research.

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
   Patient charts in VCU Cerner and VCU Dental Axium.

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

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
   - [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
   - [ ] Limited Data Set
   - [ ] Waiver of Authorization
   - [ ] Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)
   - [x] **Signed Authorization Combined with Consent Form**
   - [ ] Signed Authorization as Stand-Alone Form

Institutional Requirements Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- ⑧ DOCUMENTS

Click Continue below to go to the next section

HM20018316 - Elizabeth Bortell
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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.

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Documents Complete

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- **INSTITUTIONAL REQUIREMENTS**
- **DOCUMENTS**

End of Application

Click Continue below to exit and submit this project

Bio-Medical Project Drugs

1. * **Drug:**
   2% Lidocaine with 1:100,000 epinephrine
2. * **Manufacturer:**
   Henry Schein
3. * **Select all types that apply:**

- [x] **FDA Approved and being used as approved**
- [ ] Marketed Drug/Biologic Exempt from IND
- [ ] Investigational Drug/Biologic/Supplement used as drug
- [ ] Supplement
- [ ] Over the Counter Medication
- [ ] Other (Drug or Compound Not Listed Above)

4. * **Will the doses of drug administered and the dosing schedule match FDA approved labeling:** ***(if not, include all doses and dosing schedules in the Methods)***

- (●) **Yes**
- ( ) No
- ( ) Not Applicable

5. * **Select who holds the Investigational New Drug (IND) application for the drug/biologic:**

- ( ) External to VCU Sponsor or Investigator
- ( ) VCU Sponsor-Investigator
- ( ) VCU Sponsor who is not the Investigator
- (●) **Not Required**

6. **Indicate the drug's IND number, if applicable. If the drug qualifies for IND exemption, enter "IND Exempt":**
   IND Exempt

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Parent/ Guardian Consent

2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☑	**Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of 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
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform

4. **If Other is selected, explain:**

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

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

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

☑	**Principal Investigator**

- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [x] **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
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

    - When and where consent will occur
    - What will be covered during the consent discussion
    - How the consent discussion will occur (e.g. in-person, phone, video conference)
    - How you will reconfirm consent on an ongoing basis, if applicable

Parents will be initially presented with the option to be considered to participate in the study at the end of their consultation for surgery visit. Parents will be provided with a copy of the consent form on that date. Parents will be asked to sign consent day of surgery preoperatively

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
    - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
    - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
    - [ ] Removing physical symbols of authority like white coats or police badges
    - [ ] Sitting down beside the participant instead of standing over them
    - [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
    - [ ] Moving to a more neutral location like a conference room
    - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
    - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
    - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
    - [x] **Other protection(s) not listed here – describe below**

☐ N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   All parents of patients will be given the consent forms at the day of their consultation and be given the opportunity to think about whether they would wish to participate at home with their family. Consent will be performed by a separate nurse day of surgery after consent for dental treatment under general anesthesia by the dental surgery team on that date. Families will be informed that their decision will not alter the dental care that will be rendered whether they choose to proceed or not. To help to minimize coercion we are having a separate nurse obtain consent after all other consents have already been obtained.

10. * **How much time will participants be given to make a decision:**
    Parents of patients will be asked to participate in the study at the close of their consultation for surgery. Parents of patients will have the time from the date of consultation to the day of surgery to decide if they would like to participate in the study.

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

Personnel

1. * **Name:**
   Elizabeth Bortell

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Caroline Carrico

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

- ☑ **Study Design**
- ☐ Data Collection - Lab

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Jeannette Kierce

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

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

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

   ○ Yes
   ● **No**

3. * **Roles:**

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

4. * **Study related responsibilities:**

- ☑ **Study Design**
- ☐ Data Collection - Lab

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

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

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

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

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Elizabeth Kleefisch

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

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

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

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab

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

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

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

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

7. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent 11.29.22 Clean.pdf(0.21)

Add Document

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

Add Document

1. * **Document Name:**
   Research Presentation Script and Flow Sheet
2. * **Type:**
   Research Protocol
3. * **File:**
   Research Presentation Flow- FINAL.docx(0.04)

Add Document

1. * **Document Name:**
   Research Consent Presentation and Flow Sheet
2. * **Type:**
   Research Protocol
3. * **File:**
   Research Consent Flow Sheet - FINAL.docx(0.03)

Add Document

1. * **Document Name:**
   Anesthesia Data Collection as part of Data Collection Packet

2. * **Type:**
   Research Measure

3. * **File:**
   Anesthesia flow chart.docx(0.01)

Add Document

1. * **Document Name:**
   Data collection packet
2. * **Type:**
   Research Measure
3. * **File:**
   Research Data Packet .docx(0.01)

Add Document

1. * **Document Name:**
   FDA Lidocaine
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   Lidocaine - Dental FDA.pdf(0.01)

Add Document

1. * **Document Name:**
   IND Exemption for Lidocaine
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   IND Exemption for Lidocaine.docx(0.01)

Add Document

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

Add Document

1. * **Document Name:**
   GA Post- Op Instructions
2. * **Type:**
   Other
3. * **File:**
   General Anesthesia Post- Op Instructions.docx(0.01)

Add Document

1. * **Document Name:**
   FLACC Behavior Scale
2. * **Type:**
   Research Measure
3. * **File:**
   FLACC Behavior Scale.docx(0.01)

Add Document

1. * **Document Name:**
   Parent's Post Operative Pain Measure
2. * **Type:**
   Research Measure
3. * **File:**
   Parents Post Operative Pain Measure.docx(0.01)

Add Document

1. * **Document Name:**
   MSDS Lidocaine
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   MSDS.pdf(0.01)