## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE:** The Effect of Local Anesthesia when used in Dental Restorative Cases Under General Anesthesia on Post-Operative Comfort

**VCU INVESTIGATORS:** Dr. Elizabeth Bortell (PI)
Dr. Jeanette Kierce (co-I)

*[NOTE: In this consent form, if you are a parent or legal guardian, please remember that "you" refers to the child study participant.]*

## ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you or your child and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

## AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Local anesthesia is a widely used tool to ensure patient safety and comfort in the dental office. This is usually accomplished by administering a shot of numbing medicine (local anesthesia) in different parts of the mouth. Local anesthesia is an important tool used for care in the dental office however despite its standardized use in dental clinics use of local anesthetic is not standardized for use in dental cases under GA. In the literature there is some evidence suggesting that it has some marginal benefit for pain control short term post operatively.

You are being asked to participate in this study because you have been diagnosed with diseases of tooth/teeth and have consented to its treatment that requires treatment under general anesthesia .

The purpose of this study is to compare patient responses after surgery when local anesthetic is used for dental treatment under GA and when it is not used.

The study section will have 60 participants of which one half will receive local anesthesia for restorative dental care under GA and the other half will receive conventional no anesthesia for restorative dental treatment under GA, based on random assignment (like the flip of a coin). You have an equal chance of being assigned to either group prior to the consented treatment. Before the surgery, a nurse will assess your child's overall pain and comfort. The study team (faculty, anesthesiologist, and resident) will record the blood pressure, heart rate, and breathing duration throughout the procedure. After the child has completed the surgery a nurse will again access your child's overall pain and comfort. Lastly, you will be contacted that evening of surgery by a member of the study team to check up on your child and will be asked some questions to assess your child's comfort at home.

Your participation in this study will occur on the day of your child's surgery and will last until time of discharge. Approximately 60 participants will take part in the study.

**Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.**

## WHY IS THIS STUDY BEING DONE?

Use of local anesthesia for dental restorative work under General Anesthesia is not standardized among providers.
The purpose of this study is to:

1. Evaluate patient pain, irritability and discomfort post operatively after surgery in patients when local anesthetic is used to when it is not used intra operatively during the surgery.

With this study we seek to determine if local anesthetic is a beneficial tool for use In dental cases under general anesthetic to standardize practices among dental providers.

## WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

If you are interested in this study, a member of the study team will go over the study in detail and obtain your informed consent. You will have ONE research related study visit during which you will:

1. Pre-operatively a Nurse will assess your child's comfort before surgery and give it a score.
2. Patients will be taken back for surgery to the operating room and have their dental work completed with or without local anesthetic (based on random assignment).
3. Post-operatively a Nurse will assess your child's comfort after surgery and give it a score.

4. That evening following surgery you will be contacted to check up on your child after surgery and over the phone you will be asked some questions to assess your child's comfort at home.

## WHAT ALTERNATIVE TREATMENTS OR PROCEDURES ARE AVAILABLE?

If you decide not to enter this study, you will receive the General Anesthesia and local anesthesia will be administered at the digression of the dentist providing care day of surgery.

## WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Local anesthesia is standardly used for dental care in the dental office. Local anesthesia use in the operating room is less standardized and is used based upon provider preference. There is some evidence that local anesthesia can help with post-operative pain. However, local anesthesia is also seen to have an increase in lip biting due to lack of sensation and discomfort to patients due to altered sensation. Effects of local anesthesia have a short duration and sensation quickly returns after surgery. Every patient's response is different and we hope to track that response to help the study doctors learn things that may help other people in the future.

## WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

**Possible Risks Associated with 2% Lidocaine local anesthetic use :**

Occasional: (Between 1-10% chance that this will happen)

- Headache
- Swelling
- Infection
- Nausea
- Inflammation of the gums

Rare:

- Earache
- Numbness and tingling
- Difficulty opening the mouth
- Allergic reaction
- Systemic toxicity

**Non-Physical Risks**
Participation in research might involve some loss of privacy and confidentiality. There is a small risk that someone outside the research study could see and misuse information about you.

## WHAT ARE THE COSTS?

You and your insurance plan will pay for the costs of dental care you get as part of the study, just as you would if you were getting the usual care for your condition.

## WILL I BE PAID TO PARTICIPATE IN THE STUDY?

No.

## WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

## CAN I STOP BEING IN THE STUDY?

Your participation in the study would be restricted to one study visit. You will have a choice to withdraw from the study before the start of the procedure during study visit. Since all research data is collected on this visit, you will not be able withdraw from the study after this visit is complete. Data that has already been collected about you will remain part of the study database and may not be removed.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it is necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor of the study drug has stopped the support for the study
- administrative reasons require your withdrawal

- the anesthesiologist chooses to administer Precedex or Ketolorac for pain management during the dental procedure under general anesthesia for post-operative pain management

## HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services or the Federal Food and Drug Administration

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

There are no plans to use the information gathered in this research study for any commercial profit.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

## FUTURE RESEARCH STUDIES

The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

## HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

The following types of information may be used for the conduct of this research:

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|---|---|---|
| ☒ Complete health record | ☒ Diagnosis & treatment codes | ☐ Discharge summary |
| ☒ History and physical exam | ☐ Consultation reports | ☐ Progress notes |
| ☐ Laboratory test results | ☐ X-ray reports | ☒ X-ray films / images |
| ☐ Photographs, videotapes | ☐ Complete billing record | ☐ Itemized bill |
| ☐ Information about drug or alcohol abuse | ☐ Information about Hepatitis B or C tests | |
| ☐ Information about mental health | ☐ Information about sexually transmitted diseases | |
| ☐ Other physical or mental health information (specify): | | |

### Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Data Coordinators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

## STATEMENT OF PRIVACY RIGHTS

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

## WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

**Principal Investigator:**

1. **Dr. Elizabeth Bortell, DDS.**
   Director of Pediatric Dentistry Services Brook Rd Campus,
   Associate Professor
   305, Wood Building, VCU
   School of Dentistry 521 N 11th St, Richmond, VA 23298
   Ph: (804) 228- 5895

**Co-Investigators:**

1. **Dr. Jeanette Kierce, MD DABA FAAP**
   Pediatric Anesthesiology
   VCU Medical Center Main Hospital
   1250 E. Marshall St. Richmond,
   VA 23219
   Ph: (804) 828-9205

The researchers/study staff named above are the best persons to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University
Office of Research 800 East Leigh Street,
Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

## STATEMENT OF CONSENT [AND/OR PARENT/LEGAL GUARDIAN PERMISSION]

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate [and/or give permission for my child to participate] in this research study. I will receive a copy of the consent form for my records.

| **Signature Block for Enrolling Child Participants - Parent/Guardian Permission** | |
|---|---|
| Name of Child/Youth Participant | |
| Name of First Parent/Legal Guardian (Printed) | |
| **Required** First Parent/Legal Guardian Signature | Date |
| **Optional** Second Parent /Legal Guardian's Signature | Date |
| Name of Person Conducting Parental Permission Discussion (Printed) | |
| Signature of Person Conducting Parental Permission Discussion | Date |
| Principal Investigator Signature (if different from above) | Date |

**Signature Block for Short Form Consent – Participants with Limited English Proficiency**

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Name of Participant (Printed)

_____ _____

Witness or Interpreter's Signature Date

*(NOTE: The witness may be the interpreter or a family member of the LEP subject who can speak both English and the participant's language. The witness cannot be the member of the study team conducting the consent process.)*

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Name of Person Conducting Consent/Assent Discussion (Printed)

_____ _____ Signature of

Person Conducting Consent/Assent Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date