# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** *Peri-operative oral pain control following buccal graft urethroplasty: Randomized control trial of harvest site anesthetic*

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This is a clinical research study about oral pain control following buccal graft urethroplasty. Your study doctor(s), Lindsay Hampson, MD, Benjamin Breyer, MD, and Nathan Shaw, MD from the UCSF Department of Urology, will explain the study to you.

## STUDY SUMMARY

**Introduction:**

We are asking you to consider taking part in a research study being done by Lindsay Hampson, MD, Benjamin Breyer, MD, and Nathan Shaw, MD at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

**Purpose of the study:**

Patients undergoing buccal urethroplasty will often have significant post-operative oral pain from the graft site. The purpose of this study is to assess three established anesthetic protocols for oral pain control in order to determine which is the most effective at oral pain reduction.

**Study Procedures:**

If you choose to be in this study, you will be randomly assigned to one of three groups, all following established but slightly different anesthetic protocols for oral pain. You will then be given a study tracking worksheet to record your medication usage, and you will be asked to complete a pain scale assessment over the phone 3 times (on post-operative days 1, 5, and 10).

You will be in this study until 10 days after surgery and visit the research site approximately once for your scheduled procedure.

**Possible Risks:**

There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Post-operative oral pain, as part of standard urethroplasty buccal graft surgery
- The regimen may be less effective than other available interventions
- Leakage of personal health information if privacy is breached

We'll tell you about the other risks later in this consent form.

**Possible Benefits**:

You may benefit from participating in the study if the regimen you receive provides improved pain control compared to what you might otherwise have received, but this cannot be guaranteed.

**Your Other Options:**

You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.
- Getting no treatment

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

## DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are undergoing anterior urethroplasty with buccal grafting.

**Why is this study being done?**

The purpose of this study is to compare three established anesthetic protocols used during buccal urethroplasty in order to determine which, if any, is best at reducing post-operative oral pain.

Drugs/procedures that will be used in this study, as standard of care, include lidocaine, epinephrine, ibuprofen, Tylenol, oxycodone, and Magic Mouthwash or peridex.
Drugs/procedures that will be used in this study depending on the group the patient is placed in include: Marcaine and buccal block.

This study is investigator initiated and unfunded. None of the investigators have any financial or proprietary interests in the findings of this study.

**How many people will take part in this study?**

About 60 people will take part in this study. Each of the three groups in the study will consist of around 20 participants.

**What will happen if I take part in this research study?**

If you choose to participate in this study, you will be placed in one of three groups of patients undergoing buccal urethroplasty. You will be "randomized" into one of the study groups. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have a one in three chance of being placed in any group. Each group will receive a different anesthetic protocol (method of providing pain control) during the procedure, but all of the protocols are routinely done in patients who are having this type of surgery. Simply put, all groups will undergo standard of care, but Group 2 will receive an additional long acting local anesthetic, and Group 3 will receive an additional buccal block. Post-operatively, participants will also be assigned to receive either Magic Mouthwash or Peridex 1:1 within each group.

**Group 1's protocol**: Basic buccal procedure

**Group 2's protocol**: Basic buccal procedure + Long acting local anesthetic

**Group 3's protocol**: Basic buccal procedure + Buccal block

After your surgery, you will then be asked to complete a pain scale assessment over the phone at 3 time points: post-operative days 1, 5, and 10. You will also be given a study tracking worksheet to record how many of each pain medication you take in a day.

**How long will I be in the study?**

You will be in the study until 10 days after your surgery, once you have completed your final pain scale assessment over the phone,

**Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the anesthetics can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to this study are minimal and include:

**Likely**

- Risks normally associated with buccal urethroplasty that you would have regardless of your participation in this study, such as post-operative oral pain and bleeding. Please contact your regular provider/surgeon if you have any questions about the risks of the procedure.
- Randomization risks: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatments or other available treatments

**Less Likely**

- Breach of personal health information

**Rare but serious**

- Allergic reaction to a medication
    - Bupivacaine risks include: itching, numbness, chest pain, fever, mood changes, seizures
    - Lidocaine/epi toxicity risks include: seizure, coma, hypotension, atrioventricular heart block, idioventricular rhythms, ventricular tachycardia and fibrillation, cardiovascular collapse and death
- Accidental IV injection of the local anesthetics/epi
- For buccal block procedure: possible intravascular injection of the medication(s), lidocaine toxicity, pain at injection site, poor anesthetic response, bleeding, bruising, prolonged numbness, temporary facial weakness

**Unknown Risks:** The drugs and procedures used in this study may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study. For more information about risks and side effects, ask your study doctor.

**Are there benefits to taking part in the study?**

The group you are assigned to may utilize an anesthetic protocol that proves to be more effective at decreasing post-operative oral pain than you might otherwise have received. Additionally, while not a direct benefit to you, your participation in this study will help doctors learn more about pain management for buccal urethroplasties, and it is hoped that this information will help in the treatment of future patients with urethral stricture disease.

**What other choices do I have if I do not take part in this study?**

Your other choices may include:

- Getting treatment or care without being in a study.
- Taking part in another study.
- Getting no treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

**How will my information be used?**

Researchers will use your information to conduct this study. Once the study is done using your information, we may share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the

researchers know who you are. We will not ask you for additional permission to share this de-identified information.

**How will information about me be kept confidential?**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the FDA

**Are there any costs to me for taking part in this study?**

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

If you have questions about what costs you will be responsible for, please talk with the study investigator before deciding to enroll in the study. Depending on the type of study, some of your costs could be substantial.

**Will I be paid for taking part in this study?**

You will not be paid for taking part in this study.

**What happens if I am injured because I took part in this study?**

It is important that you tell your study doctor, Lindsay Hampson, MD, Benjamin Breyer, MD, or Nathan Shaw, MD, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 415-353-2200.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

**What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

**Who can answer my questions about the study?**

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Lindsay Hampson, MD, Benjamin Breyer, MD, and Nathan Shaw, MD at 415-353-2200.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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 Web site will include a summary of the results. You can search this Web site at any time.

## CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

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| Date | Participant's Signature for Consent |
| Date | Person Obtaining Consent |