CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Regional Block for Postoperative Free Flap Care

UAB IRB Protocol #: IRB-300003574

Principal Investigator: Anthony Morlandt, MD

Sponsor: UAB Department of Oral and Maxillofacial Surgery

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to determine if receiving extra pain medication during your head and neck surgery effects the amount and kind of pain medication that is taken after surgery.
Duration & Visits	You will be in this study for up to 21 days.
Overview of Procedures	If you decide to take part in this study, you will assigned by chance to one of the treatment groups. This is called randomization. • If you are picked for the **Treatment Group**, you will receive ropivacaine 0.2% before, during, and after your surgery, during your hospital stay only. • If you are picked for the **Control Group**, you will not receive any local anesthetic during your surgery. Both groups will have surgery (including anesthesia) in the routine manner that planned for you, based on your condition. Those in the Treatment Group will receive extra medication before and during their surgery, while those in the Control Group will not receive any extra medication during their surgery. Both groups will receive the same post-operative prescription pain medications (oxycodone or morphine, acetaminophen, ibuprofen), will complete a daily pain diary (recording pain score and medications taken), and will have a prescription pain medication pill count at the first post-operative clinic visit.
Risks	You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives. The most common side effects of the medications include nausea/vomiting, constipation, dizziness, itching, rash, and headache.
Benefits	You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat post-surgical pain in the future.
Alternatives	You do not have to participate in this study to receive standard of care treatment for your head and neck disorder. Your doctor will tell you more about other treatments that may be available to you. You may choose to have no treatment at all. One alternative may be to not to participate in this study.

Purpose of the Research Study

We are asking you to take part in a research study because you are scheduled to have surgery for your head and neck disorder. You will be given a prescription for opioid and non-steroid anti-inflammatory pain medications (NSAIDs) as part of your routine care after your surgery. The purpose of this research study is to determine if receiving extra pain medication (a regional pain block) before and during your surgery effects the amount and kind of pain medication that is taken after surgery.

There will be 50 participants enrolled at UAB.

Study Participation & Procedures

If you agree to join the study, your medical record will be reviewed to obtain information regarding your medical condition and diagnosis, as well as demographic information, such as your age and gender.

You will be randomly picked (like the flip of a coin) to receive either the study intervention, or to receive the standard of care treatment during your surgery:

- If you are picked for the **Treatment Group**, you will receive ropivacaine 0.2% prior to, during, and after your head and neck surgery, during your hospital stay.
- If you are picked for the **Control Group**, you will not receive any local anesthetic during your head and neck surgery.

You will then have your surgery. This surgery will be performed in the routine manner that was planned for you, based on your condition.

If you are picked for the **Treatment Group**, you will have a catheter placed prior to your surgery. This is considered routine for all patients who receive pain blocks for head and neck procedures. You will receive the extra medication during the procedure, and for 3-5 days following your procedure while you are in the hospital. The catheter will be removed before you are discharged from the hospital.

If you are picked for the **Control Group**, you will not have the catheter placed, and you will not receive any extra medication during or after the procedure.

After your surgery, you will be prescribed pain medication in the routine manner. These are the same medications that you would have whether you were participating in this study or not. While you are in the hospital, we will collect information on your use of pain medication from your medical record. You will also be asked to complete a pain scale, graded on a scale of 1-10, three times a day while you are in the hospital.

For study purposes, you will be given a study diary to complete when you are discharged from the hospital. This will consist of the pain scale listed above, as well as a medication diary. You will be asked to record all of the medications you take for the pain you experience after your surgery.

At your first post-operative clinic visit (Day 14-21), you will bring in your study diary and your medicine bottles so that we can count the number of pills you have left on your prescriptions. We will record these amounts for our research data only.

The daily study diary will take approximately 5 minutes per day to complete. The total amount of time you will be in the study is up to 21 days, depending on when your first post-operative clinic visit is scheduled.

Risks and Discomforts

All of the drugs to be used in this study are FDA-approved, commonly-used, widely available, generic medications. These drugs will be used at their standard dosing for their approved indications.

If you are picked for the **Treatment Group**, you will receive extra pain medication before or during your surgery.

The most common side effects of ropivacaine 0.2% (Naropin®) are:

- nausea/vomiting
- headache
- fever
- itching
- confusion
- tinnitus, or ringing in the ears
- altered or impaired sense of taste
- irregular heart rhythms

There is no additional risk to taking ropivacaine as part of this study. It does not have cross reactions or other known interactions that may lead to increased risks, other than those listed above.

No matter what group you are assigned to, you will receive prescriptions for oxycodone, acetaminophen (commonly known as Tylenol), and/or ibuprofen (commonly known as Advil or Motrin) for any post-operative surgical pain you may have. During your stay in the hospital after your surgery, you may be given morphine in an IV for your pain.

Risks associated with oxycodone include:

- constipation
- nausea/vomiting
- sleepiness
- dizziness
- itching
- headache
- dry mouth

Risks associated with acetaminophen include:

- liver damage/failure
- headache
- nausea
- itching

Risks associated with ibuprofen include:

- nausea
- heartburn
- diarrhea
- abdominal pain
- constipation
- bloating
- dizziness

- headache
- rash
- tinnitus, or ringing in the ears

Risks associated with morphine (IV) include:

- Nausea/vomiting
- Constipation
- Lightheadedness
- Dizziness
- Drowsiness
- Increased sweating
- Dry mouth
- Pain, redness, or swelling at the injections site

There is no additional risk to taking these medications as part of this study. There aren't any known increased risks for taking these medications in combination. They do not have any cross reactions with each other or other known interactions that may lead to increased risks, other than those listed above.

All surgical procedures will be performed in the routine manner. There will be no additional clinical or surgical risks, other than the normal risks for patients undergoing this type of treatment.

There is a risk of a loss of confidentiality for patients involved in research studies. All of your personal and medical information will be stored in a locked area. Only qualified research staff will have access to this information. Once your research data has been collected, all information that could link your personal identity to your medical information will be deleted. There will be no personally identifying information used to report any findings from this study.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives. There is a chance that those assigned to **Control Group** (who will not the extra pain medication prior to or during the surgery) will have an increase use of this post-operative pain medication.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g.,

treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

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

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children’s of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children’s of Alabama and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal
Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There will be no cost to you for taking part in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation
You will not be paid to participate in this study.

Payment for Research-Related Injuries
UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Questions
If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Morlandt at (205) 996-2799 or after hours by paging him at (205) 934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures
Your signature below indicates that you have read (or been read) the information provided above, and that you agree to participate in this study. You will receive a copy of this signed consent form.

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Signature of Participant Date

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Signature of Person Obtaining Consent Date