Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: Meloxicam for Postoperative Pain in Mohs Micrographic Surgery

Sponsor: University of Oklahoma, Department of Dermatology

Principal Investigator: Lindsey Collins, MD

Phone Number: 405-271-6110

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY AM I BEING ASKED TO PARTICIPATE IN THIS STUDY?

You are being invited to participate because you are undergoing Mohs micrographic surgery, and we are studying postoperative pain management options.

WHAT IS THE PURPOSE OF THIS STUDY AND HOW LONG WILL IT LAST?

The purpose is to evaluate three pain management strategies to determine the most effective option for controlling pain while minimizing side effects. Your participation will involve a follow-up survey completed 7–21 days after surgery.

WHAT WILL I BE ASKED TO DO IF I PARTICIPATE?

If you decide to participate in this study, you will be asked to:

- Be randomly assigned to one of three groups:
  - Group 1: One dose of Meloxicam 7.5 mg with as-needed acetaminophen.
  - Group 2: One dose of Meloxicam 15 mg with as-needed acetaminophen.
  - Group 3: Standard care with acetaminophen alternating with ibuprofen.
- Record your pain levels on a scale of 0–10 on the day of surgery and the following day.
- Complete a satisfaction survey during your follow-up visit.

WHY MIGHT I WANT TO PARTICIPATE?

While there may or may not be direct medical benefit to you, your participation may help improve pain management strategies for future patients.

WHY MIGHT I NOT WANT TO PARTICIPATE?

The risks include medication side effects:

- **Meloxicam**: Possible gastrointestinal upset, bleeding, kidney injury, or liver injury.
- **Acetaminophen and Ibuprofen**: Risk of GI upset or liver damage, especially with excess use.

You may also find the study procedures inconvenient.

WHAT OTHER OPTIONS ARE THERE?

Your other options are to continue with standard of care postoperative pain management which is alternating acetaminophen and ibuprofen as needed for pain. Please talk to your surgeon about these and other options.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There is no cost to you for participating in the study.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Approximately 300 patients will participate in the research study.

WHAT IS THE STATUS OF THE [DRUGS/DEVICES/PROCEDURES] USED IN THIS STUDY?
Meloxicam, ibuprofen and acetaminophen are an FDA-approved drug commonly used to manage pain and inflammation. The dosages in this study are within the approved range for safety.

WHAT IS INVOLVED IN THE STUDY?
You will be randomized to receive either a one-time dose of meloxicam (7.5mg or 15mg) with as needed acetaminophen (500mg) every 3 hours or be placed in the standard of care group which is acetaminophen (500mg) alternating with ibuprofen (200mg) every 3 hours.

Randomization means that you are put in a group by chance. You have a **1 in 3** chance of being in any one of the 3 treatment groups, like rolling dice. A computer program at the study sponsor will make this random assignment.

You will receive the one time dose of meloxicam (7.5mg or 15mg) or a one time dose of acetaminophen (500mg) in the office.

You will fill out a form after your surgery rating the pain that you have on a 0-10 scale.

You will fill out a patient satisfaction form when you get your sutures removed and wounds checked, approximately 7-21 days after your surgery.

WHAT ARE THE RISKS OF THE STUDY?
Participants in this study will receive one of the following pain control regimens:

- A one-time dose of oral **Meloxicam 7.5 mg** with as-needed acetaminophen.
- A one-time dose of oral **Meloxicam 15 mg** with as-needed acetaminophen.
- Standard care with alternating **acetaminophen (Tylenol)** and **ibuprofen (Advil)**.

Below is a discussion of the physical and non-physical risks associated with these medications, ranked by likelihood of occurrence and severity.

Meloxicam (one-time dose, 7.5 mg or 15 mg) and Ibuprofen (200mg every 3 hours)

Meloxicam and Ibuprofen are a non-steroidal anti-inflammatory drug (NSAID). Since participants will receive only a single dose of meloxicam, the likelihood of adverse effects is low, and serious side effects are extremely rare. Ibuprofen, is another NSAID, used here as part of standard care in alternating doses with acetaminophen. Chronic use of Ibuprofen has been shown to have increased risk of side effects

Expected risks (occasional):

- **Mild gastrointestinal discomfort**, such as nausea, heartburn, or indigestion.

Expected risks (rare):

- **Mild gastrointestinal discomfort**, such as upset stomach, nausea, or heartburn.

Less likely but serious risks (extremely rare):

- **Allergic reaction** (e.g., rash, itching, swelling, or difficulty breathing).
- **Bleeding, ulceration, or perforation of the stomach or intestines** (typically associated with prolonged NSAID use).
- **Cardiovascular risks**, such as a heart attack or stroke, are rare and primarily associated with long-term NSAID use.
- **Kidney dysfunction and injury** in individuals with preexisting kidney problems or dehydration. As well as individuals who take NSAIDs chronically.

Ramifications:
In the rare event of an allergic reaction or gastrointestinal bleeding, medical intervention would be necessary. Given the single-dose nature of this study, these risks are highly unlikely to occur. Serious side effects are uncommon with short-term use of Ibuprofen. Participants should follow the study dosing guidelines to minimize risks.

Pregnancy risk:
NSAIDs like Meloxicam and Ibuprofen may harm an embryo or fetus. If the participant is or becomes pregnant, there may be unforeseeable risks. Women who are pregnant or breastfeeding should not participate.

Acetaminophen (Tylenol)
Acetaminophen is generally considered safe when used as directed.

Expected risks (rare):

- **Mild allergic reaction**, such as rash or itching.

Less likely but serious risks (very rare):

- **Liver damage**, which is most often associated with exceeding the recommended dose or in individuals with preexisting liver conditions.

Ramifications:
Participants should not exceed the recommended dose of acetaminophen to avoid liver-related side effects.

REPRODUCTIVE RISKS FOR WOMEN AND MEN:
If you are a female, you must not be and should not become pregnant nor breast-feed an infant while on this study. Taking the study drug(s) or undergoing a particular procedure or treatment involved in

this study while you are pregnant or breastfeeding may involve risks to an embryo, fetus, or infant, including birth defects which are currently unforeseeable.

IN CASE OF PREGNANCY:
If you become pregnant or suspect that you are pregnant, or (for males) if you make someone pregnant during this study, you should immediately inform the study personnel. If you become pregnant or suspect that you are pregnant while on this study, tell the study doctor immediately; the study doctor will perform a pregnancy test. The study drug may be discontinued until the result of the pregnancy test is known. If pregnancy is confirmed, you may be withdrawn from the study. The study doctor will assist you in getting obstetrical care at your cost. The study doctor and the Sponsor will follow the progress of your pregnancy and will request access to your and/or your infant's medical records for least eight weeks after delivery. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

General statement on unforeseen risks:
This study involves commonly used medications with well-documented safety profiles. However, there is a small chance of unforeseeable risks, particularly if participants have undisclosed health conditions or medication interactions.

For more information:
Please contact the researcher or refer to the attached pharmaceutical information sheets for detailed descriptions of risks and side effects.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

Your information related to your surgery will be collected as part of the research, and will not be be used or distributed for future research studies.

CAN I WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. There are no consequences of your decision to withdraw from the research study, but your data will not be collected for the project if you withdraw.

There may be circumstances under which your participation may be terminated by the investigator without your consent:

- If you do not complete the numeric pain scale sheet correctly and in a timely manner
- If you do not complete the patient satisfaction survey correctly and in a timely manner within 7-21 days of the surgery
- The study is stopped by the sponsor.
- Your postoperative pain worsens.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?
In the case of injury or illness results from this study, emergency medical treatment is available.

Your insurance will be billed for treatment.

Complications arising as a result of the natural progression of an underlying or pre-existing condition will be billed to you or your insurance. Please check with the investigator or with your insurance company if you have questions.

No other funds have been set aside by the University of Oklahoma Health Sciences Center or OU Health to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. Please be sure to discuss leaving the study with the principal investigator. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?
If you have questions, concerns, or complaints about the study or have a research-related injury, or if you need to schedule another appointment, please call the office at 405-271-6110 ext: 48009. If it is after 4:00 PM Monday through Friday or on the weekends, please page the resident on call at 405-271-4700. Ths 405-217-4700 phone number is a 24 hour service.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and for questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

SIGNATURE:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18)	**Printed Name**	**Date**
SIGNATURE OF PERSON	**Printed Name**	**Date**