	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 6/6/2019)	DATE: MRN: NAME:
APPROVED **January 19, 2022** INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** Non-Opioid Pain Control Regimen after Open Reduction Internal Fixation of the Clavicle	

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1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study. Participation is voluntary. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to evaluate the effectiveness of post-operative pain control without using narcotic pain medication following open reduction and internal fixation of the clavicle. **Duration**. It is expected that your participation will last 4 weeks and will consist of 2 post-operative clinic visits at 2 weeks and 4 weeks after surgery. **Procedures and Activities**. You will be asked to log and document your pain level on a provided pain diary and record the number of pain medication you are taking. **Risks**. It is not expected that you will have any complications or discomforts form being in this study. There may be risks or discomforts no known at this time. Detailed

information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include improved pain control, decreased risk of nausea, vomiting, or constipation (caused by narcotics) and overall increased comfort following surgery.

Alternatives. As an alternative to participation, you could choose to proceed with the standard post-operative pain medication regimen (Norco tablets).

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The Henry Ford Health System (HFHS) investigator(s) on this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

This study is being conducted to evaluate the effectiveness of post-operative pain control without using narcotic pain medications. Due to the risks of narcotic pain medication including nausea, vomiting, risk of opioid addiction, we are hoping to minimize the burden of narcotics on patients after surgery. We will be comparing the effectiveness of a narcotic free pain regimen to a standard pain regimen. This study is being supported from funding provided by the Henry Ford Health System Department of Orthopedic Surgery.

To make reading this consent form easier, the word "you" refers to you or your child (if a minor throughout the consent form.

This study is attempting to demonstrate that pain medication regimen without narcotics (also called Opioids) is equally effective (or superior) at controlling your pain after surgery. You have been chosen because you are undergoing a **Open Reduction Internal Fixation of the Clavicle**. The standard

pain medication is often Oxycodone 5mg. This medication is an opiate that provides pain relief. Patients using NON-narcotic (non-opiate) medication to control pain will use the following medication instead:

- Ibuprofen (Anti-inflammatory medication)
- Pregabalin (Non-narcotic nerve pain medication)
- Acetaminophen (Non-narcotic pain medication)
- Tizanidine (Anti-muscle spasm medication)

In the prescribed dose, these medications are safe, effective and have no addictive traits.

You have been asked to take part in a research study because you will have an Open Reduction Internal Fixation of the Clavicle. The purpose of this research study is to compare pain control after surgery between two regimens: narcotic (or opioid) based regimen and a non-narcotic (opioid-free) regimen.

There will be approximately 75 people in this research study at Henry Ford Health System (HFHS). This study will be conducted at Henry Ford Health System sites only.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin). Your doctor will not know which treatment you are receiving. This is to reduce the effect of bias on the results.

If you are in the narcotic group, you will be provided the standard 60 tablets of Oxycodone 5mg to be taken every 4 to 6 hours as needed for pain control.

If you are in the non-narcotic group you will follow a pain medication schedule that is outlined below and on the attached medication schedule:

Extra and Experimental
Postoperative Day 1:

1. Ibuprofen
    a. 800 mg every 6 hours; not to exceed 3200 mg/day
2. Pregabalin
    a. 75mg every 12 hours
3. Acetaminophen
    a. 1000mg by mouth, every 8 hours as needed for pain
4. Tizanidine
    a. 4mg by mouth every 6 hours

Discharge Medication, Weeks 1 and 2:

1. Ibuprofen (for 2 weeks)
    a. 800 mg every 6 hours; not to exceed 3200 mg/day

2. Pregabalin 75mg twice per day for 5 days then wean off as described below
    a. Dispense: 30 tablets at discharge (75mg/tablet)
    b. Wean from Gabapentin
        i. Days 6-7: morning-75mg; evening- 75mg
        ii. Days 8-9: morning-75mg
        iii. Days 10: No more Lyrica
3. Acetaminophen 1000 mg three times per day
    a. Do not exceed a total of 4 grams of Acetaminophen per day.

4. Tizanidine 4 mg every 6-12 hours for 2 weeks

Weeks 2 – 4:

1. Acetaminophen 1000 mg three times per day
    a. Do Not exceed a total of 4 grams of Acetaminophen per day.

These medications are **NOT** experimental and are both FDA approved and frequently used to control pain after surgery. The protocol of using these medications without narcotics is experimental and will be compared to the standard protocol of using only Oxycodone 5mg tablets.

If pain is uncontrolled, patients may call in for a prescription for Oxycodone 5mg for breakthrough pain. The number of narcotic tablets taken will be recorded. Patients can call the resident on call, available 24-hours per day, if additional pain control is needed. The resident can be reached by calling (313) 916-2600 and requesting to speak to the Orthopedic Surgery resident on call.

During your post-operative recovery period you will log and document your pain level on the provided pain diary and record the number of pain medications you are taking.

The details of your instructions after surgery are as follows:

- Each day you will record your pain level on a scale of 10 on a diary provided to you at the time of surgery.
- You will also **document how many tablets of each medication** you are taking to provide an accurate log of the medications that are needed. The form to document these tablets will be provided to you.
- Each evening before you go to bed, you will record your pain level on a scale of 10 on a diary provided to you at the time of surgery.

You will see Dr. Hakeos or one of his partners in the office after surgery at the standard 2 week and 4 week intervals. Each post-operative visit lasts approximately 15 minutes and at these visits you will turn in your pain diary for record keeping.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

Side effects: include low blood pressure, fecal incontinence (less than 1%), urinary incontinence (less than 1%), urinary retention (1.4% to 4.8%), oliguria (producing abnormally small amounts of urine) (1% to 5%) due to the medication Ropivacaine. If in the narcotic group, side effects of oxycodone include nausea, vomiting, constipation, dry mouth, lightheadedness, dizziness, or drowsiness. Serious but rare side effects include respiratory depression. Within the non-narcotic group, side effects of acetaminophen include headache, allergic skin reactions and upset stomach. Most common side effects of Ibuprofen are gastrointestinal including nausea, vomiting, diarrhea and upset stomach. Gastrointestinal bleeding can also occur but is less likely effect. Pregablin can cause headache, dizziness, and trouble sleeping. Serious but less likely side effects include increased suicidal thoughts, swelling of ankles and feet and chest pain. Finally, common side effects of Tizanidine include blurred vision, constipation, dizziness, dry mouth and tiredness.

The researchers will try to minimize these risks by taking a thorough history of any previous use of this medication and any adverse side effects that were experienced.

It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

All medications are FDA approved and currently used for pain control after surgery. Each medication carries side effects and should be taken only in the approved dosages. Taking medication in excess of the recommended amounts can cause side effects or other harmful effects. We recommend you do not exceed the guidelines for pain control outlined by our protocol.

There may be additional risks or discomforts that are not known at this time.

It is possible that you may encounter increased pain during your recovery period if you are in the non-narcotic pain group. To avoid unnecessary discomfort, we will provide you a small amount of narcotic tablets as a back up for excess pain.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: improved pain control, decreased risk of nausea, vomiting, or constipation (caused by narcotics) and overall increased comfort following surgery. You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

You do not have to participate in this study.

- You may choose to proceed with the standard post-operative pain medication regimen (Norco tablets).
- If you were not participating in this study, you would still have the same post-operative visit schedule and no changes to your usual post-operative care.
- There are no additional benefits to the standard treatment.
- The risks of not participating in the study may include nausea, vomiting, or constipation related to narcotic medications.
- You may also choose to take no pain medication if you are not having any post-operative pain.

Talk to your doctor about your choices before you decide if you will take part in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and

only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers. Records will be kept until study publication or if the data is unused for six months.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

10. WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Hakeos, or his staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. Okoroha by phone at (313) 205-5349 or by email at whakeos1@hfhs.org. Medical treatment is available to you in case of an injury. You can also contact the resident physician on call 24/7 by using the following number (313) 916-2600 and requesting to speak to the orthopedic surgery resident on call.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

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.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

13. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

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DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Signature of Subject	Date	Time

_____

Printed Name of Subject

_____	_____	_____
Witness to Signature	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____

Printed Name of Person Obtaining Consent