A Non-Opioid Multimodal Pain Protocol Achieves Equivalent Pain Control After Total Shoulder Arthroplasty: A Randomized-Controlled Trial

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1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

The United States is in the midst of an ongoing opioid crisis. In 2019, approximately 153 million opioid prescriptions were dispensed (46.7 per 100 persons) and 50,000 people died from opioid-involved overdoses.[1] Orthopaedic and spine conditions account for 27.7% of opioid prescriptions and prior studies demonstrate that muskuloskeletal pain is frequently reported by opioid abusers as their initial reason for consuming opioids.[2] For these reasons, orthopaedic surgeons are uniquely posed to combat this crisis.

Multimodal pain control is a strategy that utilizes multiple pain medications to provide analgesia. The theory behind this strategy is that agents with different mechanisms of action work synergistically to reduce pain by blocking multiple pain pathways. Several randomized controlled trials have investigated the efficacy of multimodal pain control for orthopaedic procedures, including anterior cruciate ligament reconstruction, labral repair, meniscus repair, and rotator cuff repair.[3-6] In these studies, patients who received a multimodal nonopioid regimen had equivalent or better postoperative pain control compared to a standard opioid regimen. Furthermore, no severe side effects were reported in patients who received the multimodal nonopioid regimen.

This randomized, single blinded, standard of care-controlled clinical trial aims to investigate the efficacy of a multimodal pain control (similar to the regimen utilized in the aforementioned studies) for controlling pain following shoulder arthroplasty. Adult patients indicated for anatomic or reverse total shoulder arthroplasty will be randomized to either the experimental or comparison group. The experimental group will receive a multimodal, non-narcotic pain control regimen consisting of Celecoxib, Pregabalin, and Tramadol preoperatively; Dexamethasone, Acetaminophen, Ropivicaine, Epinephrine, and Ketorlac intraoperatively; and Dexamethasone, Pregabalin, Tizanidine, Magneisum, Ibuprofren, and Acetaminophen postoperatively. In addition to the aforementioned multimodal pain control regimen, the comparison group will receive a standard prescription of Percocet to be taken as needed postoperatively. If patients in the experimental group feel their pain is uncontrolled, they have the option of calling in to request a perscription of Percocet.

Pain, pain medication use, and medication side effects will be closely monitored for the first 10 days after surgery by having patients respond to daily automated text messages. Additionally, all study participants will complete patient-reported outcome measures (PROMs) surveys and undergo physical examination of their shoulder during routine clinic visits preoperatively and at 1 week, 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively.

The primary outcome of this study is postoperative pain scores on the Numerical Rating Scale (NRS) for the first 10 days postoperatively. We hypothesize that there will be no significant difference between the groups with regard to the primary outcome.

Secondary outcomes measured during the first 10 days postoperative include morphine milligram equivelanets (MMEs) of opioids consumed, Patient-Reported Outcome Measurement Information System Pain Interference (PROMIS-PI) score at first postoperative clinic visit (7-10 days postoperatively), duration of patient reported adverse events (ie, constipation, nausea, diarrhea, upset stomach, drowsiness, loopiness), perioperative complications, and satisfaction with pain control. Secondary outcomes measured at routine postoperative clinic visits out to 2 years after surgery include postoperative complications, need for revision surgery, PROM

scores (ie, PROMIS UE, PROMIS PI, PROMIS D, ASES, SAS, Constant-Murley), hospital and emergency department readmission (30-day, 60-day, 90-day), duration of narcotic pain medication use shoulder strength, and shoulder range of motion.

2. SUBJECT POPULATION AND ELIGIBILITY

Subject Population

Inclusion criteria:

- Age >18 years
- Consented and scheduled for primary anatomic or reverse total shoulder arthoplasty at a Henry Ford

  hospital location.

  Exclusion criteria:

- Unable to receive or reply to mobile phone text messages
- Unable to read or speak English
- Medical history of known allergies or intolerance to any of the medications prescribed as a part of this

  study (ie, Percocet, Ibuprofren, Pregabalin, Dexamethasone, Acetaminophen, Tizanidine, Magnesium,

  Celecoxib, Tramadol, Ropivicaine, Epinephrine, Ketorlac)

- Substantial alcohol or drug abuse
- Recent or current pregnancy
- History of narcotic use within 3 months prior to surgery
- Renal or hepatic impairment or dysfunction
- Use of blood thinner medication
- Peptic ulcer disease
- Gastrointestinal bleeding
- History of gastric bypass surgery

  Patients who present to a Henry Ford orthopaedic clinic associated with a surgeon participating in this study and are indicated and consented for anatomic or reverse shoulder arthroplasty will be assessed for eligibility. Patients will be interviewed and their medical chart reviewed to determine whether they meet inclusion and exclusion criteria. Patients who meet criteria for this study will be consented by the surgeon or other key study personnel. A password-protected spreadsheet stored on Henry Ford OneDrive will be used to track patients enrolled in the study and make record of patients who do not meet inclusion criteria.

3. STUDY PROCEDURES

This is a randomized, single blinded, standard of care-controlled clinical trial. All adult patients over eighteen indicated for anatomic or reverse total shoulder arthoplasty who satisfy the inclusion and exclusion criteria of this study will be eligible. The multimodal, non-narcotic postoperative pain control regimen described below was chosen based on previous studies in non-narcotic postoperative management.[3-6]

Patients will be consented and recruited according to the inclusion and exclusion criteria described above at their preoperative visit prior to their scheduled surgical date. Once participation has been determined and consent obtained, patients will be randomized with a 1:1 allocation by use of randomization computer software (MD Anderson Cancer Center, Houston, TX, USA).

This study involves two treatment arms:

1. 1) Multimodal, Non-Narcotic (experimental group)
2. 2) Multimodal Plus Narcotics (comparison group)

Multimodal, Non-Narcotic: This group will be given the preoperative, intraoperative, and discharge medications described below. This group will not receive any opioid-containing medications, such as Percocet.

Multimodal Plus Narcotic: This group will be given the preoperative, intraoperative, and discharge medications described below. Additionally, this group will be given at the time of discharge 60 pills of Percocet 5 mg/325 mg (oxycodone hydrochloride 5mg and acetaminophen 325 mg) to be taken every 4 to 6 hours as needed.

The medications listed below will be given to all patients, regardless of which treatment arm they are randomized to.

All patients will be given the following preoperative pain medications:

1. Celecoxib (Celebrex)
a. 400 mg by mouth

2. Pregabalin (Lyrica)
a. 75 mg by mouth

3. Tramadol (Ultram)
a. 50 mg by mouth

All patients will be given the following intraoperative pain medications:

1. Dexamethasone a. 10 mg IV

2. Acetaminophen
a. 1,000 mg IV

3. Ropivicaine 5 mg/mL (0.5%) a. 300 mg local infiltration 4. Epinephrine 1 mg/mL (1:1000)

a. 1 mg local infiltration 5. Ketorolac (Tordol) 30 mg/mL

a. 30 mg local infiltration
All patients will be given the following discharge pain medications:

1. Dexamethasone
    1. 4 mg by mouth twice per day for 4 days (for same day discharge only)
    2. 10 mg IV on postoperative day 1 (for overnight patients only)
2. Pregabalin (Lyrica)

a. 75 mg by mouth twice per day for 14 days

3. Tizanidine (Zanaflex)
a. 2 mg by mouth every 6 hours for 14 days

4. Magnesium
a. 200 mg by mouth twice per day for 14 days

5. Ibuprofren (Motrin)
a. 600 mg by mouth every 6 hours not to exceed 3200 mg per day for 1 month

6. Acetaminophen (Tylenol)
a. 975 mg by mouth every 8 hours not to exceed 3000 mg per day for 1 month

If pain is uncontrolled, patients in the Multimodal, Non-Narcotic treatment arm may call in for a prescription for Percocet 5 mg/325 mg (oxycodone hydrochloride 5mg and acetaminophen 325 mg) for breakthrough pain. The number of Percocet tablets taken will be recorded.

Mosio, an automated text messaging service designed for researchers, will be used to collect data on pain levels, pain medication use, and medication side effects after the patient is discharged from the hospital. Patients will receive 5 text messages per day for a total of 10 days. The first 3 messages would be sent at 9 am, 12 pm, and 7 pm and ask patients to rate their current pain on a scale of 0-10. 2 additional text messages sent in the evening will ask patients to answer how many Percocet pills they have taken since morning and which of the following symptoms they have experienced: 1=constipation, 2=nausea, 3=diarrhea, 4=upset stomach, 5=drowsiness, 6=loopiness, 7=none.

All study participants will complete patient-reported outcome measure (PROM) surveys and undergo physical examination of their shoulder preoperatively and at 1 week, 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. Surveys include the Equinoxe upper extremity questionnaire and the PROMIS Upper Extremity (UE), Pain Interference (PI), and Depression (D) forms and the Numerical Rating Scale (NRS) pain score. The American Shoulder and Elbow Surgeons (ASES), Constant-Murley, and Shoulder arthroplasty SMART (SAS) scores will be calculated from the Equinoxe upper extremity questionnaire. Physical examination of the shoulder will be performed by the surgeon and include range of motion (degrees) and strength measurements. Shoulder strength will be evaluated using a dynamometer, hanging scale, and manual muscle testing (MMT) five-point grading scale.

Outcomes

Primary Outcome

• Postoperative pain scores on the NRS for the first 10 days postoperatively.

Secondary Outcomes

Measured during the first 10 days postoperatively

- Morphine milligram equivelanets (MMEs) of opioids consumed
- PROMIS-PI score at first postoperative clinic visit (7-10 days postoperatively)
- Duration of patient reported adverse events (ie, constipation, nausea, diarrhea, upset stomach,

  drowsiness, loopiness)

- Perioperative complications
- Satisfaction with pain control

  Measured out to 2 years postoperatively at regularly scheduled clinic visits (1 week, 6 weeks, 3 months, 6 months, 1 year, 2 years)

- Postoperative complications
- Need for revision surgery
- PROM scores (ie, PROMIS UE, PROMIS PI, PROMIS D, ASES, SAS, Constant-Murley, NRS)
- Hospital and emergency department readmission (30-day, 60-day, 90-day)
- Duration of narcotic pain medication use
- Shoulder strength
- Shoulder range of motion

  Blinding
  This is a single-blinded study, in which research personnel (eg, investigators, data collectors, and analysts) are blinded to which intervention subjects receive. Subjects will not be blinded to which intervention they receive.

Duration of Study

We expect enrollment to take approximately 1 year. Therefore, total study duration from when the first patient is enrolled to the last patient meets 2-year follow-up is 3 years.

Funding None.

Power Analysis
When the sample size in each group is 36 (72 participants in total), a two group one-sided 0.05 significance level t-test will have 80% power to reject the null in favor of the alternative hypothesis that the means of the two groups are non-inferior, assuming that the effect size is 0.6. Assuming a 10% loss to follow up, at least 80 participants are needed.

Regulatory Authority
This study will be registered on ClinicalTrials.gov prior to start of enrollment. Regulatory authority will fall under the FDA.

Data Analysis and Statistical Considerations
Data anlysis will be performed by a Henry Ford statistician who will be blinded to which interventions patients received.

Continuous data will be summarized using mean and standard deviation for normally distributed variables and median with interquartile range for nonnormally distributed variables; categorical data will be reported as counts with percentages. For continuous variables, univariate 2-group comparisons will be performed using independent 2-sample t tests when the variable is normally distributed and Wilcoxon rank sum tests when the variable is non-normally distributed. For categorical variables, univariable 2-group comparisons will be performed using the chi-square test when expected cell counts were >5 and the Fisher exact test when expected cell counts were <5. The Pearson coefficient (r) will be used to establish correlation between outcome measures. Correlation strength will be defined as very high (r = 0.90-1.00), high (r = 0.70-0.89), moderate (r = 0.50-0.69), and low (r = 0.30-0.49). Repeated-measures analyses will be performed using mixed models and included the effects of time and group and the interaction between time and group. Models will then adjusted using specified variables selected a priori in an attempt to adjust for possible confounders. Predicted means resulting from the adjusted models will be plotted for the outcome variables. If needed, significant interaction effects will be analyzed using post hoc comparisons using a Tukey-Kramer P value correction. Predicted means resulting from the adjusted models were plotted for the outcome variables. Statistical significance was set at P<.05 for group comparisons and main effect testing and P<.10 for interaction testing.

4. ANTICIPATED RISKS

All patients will be included by informed consent detailing the risks and benefits of multimodal pain regimen administration. The potential loss of privacy is addressed in Section 11 as it pertains to securing confidential information in a locked file and password-encrypted files available only to the investigators. The aforementioned regimen has been used in a similar protocol with no statistically significant increase in side effects.

5. ANTICIPATED BENEFITS

Direct benefits of non-narcotic regimen may include decreased postoperative pain and oral narcotic requirement, as well as a decreased potential for narcotic addiction.

6. RENUMERATION/COMPENSATION

There is no compensation offered.

7. COSTS

No increased cost incurred by the patient. All costs outside of standard care will be incurred by departmental research funds.

8. ALTERNATIVES

The alternative to study inclusion (no randomized treatment) will be presented as a perfectly reasonable course of action. There are no other known alternatives for achieving appropriate post-operative pain control following a total shoulder arthroplasty. Patients may not participate in the study if they do not wish to participate.

9. CONSENT PROCESS AND DOCUMENTATION

Patients will be presented with consent for the clinical trial at the time of surgical consent, always performed during the final preoperative office prior to the surgical date. The subject will have the duration of the office visit to decide on participation. Understanding will be ascertained using the teach-back method of informed surgical consent. Language used in the surgical consent will mimic a sixth grade reading level. The patient must be able to verbally state their diagnosis and planned intervention. The risks and benefits of the proposed treatment will be detailed and the patient must repeat these back to the person obtaining consent. Voluntary withdrawal at any point will be stressed. The alternative to study inclusion (no randomized treatment) will be presented as a perfectly reasonable course of action. Patients will be allowed unlimited time to ask and have their questions answered by a physician involved in the study.

10.WITHDRAWAL OF SUBJECTS

Subjects will be withdrawn from the study if they are unable to tolerate any of the medication prescribed. Data collection on patients who were withdrawn will be terminated and data destroyed.
Patients may withdraw from the study at any time for any reason without affecting the quality of their care.

11.PRIVACY AND CONFIDENTIALITY

Data will be stored on a password protected HFH computer. Patient data will either be located in the chart or kept in a locked spreadsheet that contains no patient identification aside from a unique patient ID associated with their MRN. This will only be accessible to the investigators. Data will be destroyed following publication or after six months of inactivity. We will also obtain HIPAA authorization in order to access the medical record.

Mosio, the automated text messaging service we plan to use to assess pain, pain medication use, and medication side effects after discharge, maintains compliance requirements according to HIPAA and 21 CFR Part 11 standards. Patient data in Mosio is password protected. Access to Mosio will only be granted to a subset of study personnel listed on this IRB who are directly responsible for either adding patients to Mosio or extracting data. Patients can be identified in Mosio only by their MRN or phone number. No other identifying information is recorded or stored in Mosio.

12.DATA AND SAFETY MONITORING PLAN

The principal investigator will perform safety monitoring. Our study does not include mortality as a major endpoint, purport to provide definitive information about efficacy of each nonnarcotic intervention, nor does prior data suggest unacceptable toxicity with the intervention. The

principal investigator will be responsible for premature cessation of the study if unacceptably high risks are incurred (uncontrolled pain, higher rates of cardiovascular or neurological events beyond hospital averages, or any other life-threatening outcomes). This is consistent with federal guidelines 21 CFR 50.24 and 45 CFR 46.111.

Unanticipated Problems and Adverse Events
We will report any problems or adverse events to the IRB via email.

13.QUALIFICATIONS OF THE INVESTIGATOR(S)

Stephanie Muh, MD. Medical Education: Drexel University College of Medicine, Philadelphia, PA. Residency: Henry Ford Hospital, Detroit, MI, Orthopedic Surgery. Fellowship: Case Western Reserve, Cleveland, OH, Shoulder and Elbow Surgery. Dr. Muh has conducted and published multiple clinical trials and has extensive experience in the academic arena.

Jared Mahylis, MD. Medical Education: University of North Dakota School of Medicine, ND. Residency: Oregon Health & Science University, Orthopaedic Surgery, OR. Fellowship: Cleveland Clinic Foundation, Shoulder Surgery, OH. Dr. Mahylis has conducted and published multiple clinical trials and has extensive experience in the academic arena.

The co-investigators are all medical students, current orthopedic residents at HFH, or attending surgeons at HFH. Each has experience with conducting medical research and has multiple recent publications in medical literature.

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	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 12/01/2021)	DATE: MRN: NAME:
	PROJECT TITLE: Multimodal Nonopioid Pain Protocol Following Shoulder Arthroplasty Surgery: A Prospective Randomized Controlled Trial	

Principal Investigator (PI): Stephanie Muh MD
PI Address: 6777 West Maple Road, West Bloomfield, Michigan 48322
PI Phone: (313) 587-3854

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 study is to evaluate the effectiveness of pain control without using narcotic pain medication following shoulder replacement surgery. **Duration**. It is expected that your participation will last approximately 2 years. **Procedures and Activities**. You will be randomly assigned to one of two groups. Group 1 will receive narcotic and non-narcotic pain medications after shoulder replacement surgery. Group 2 will only receive non-narcotic pain medications. You will be asked to respond to five text messages every day for the first 10 days after your surgery. You will also complete questionnaires at routine clinic visits with your surgeon.

Risks. It is not expected that you will have any complications or discomforts from being in this study. There may be risks or discomforts not 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. Depending on which group you are assigned, you may experience 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 not to participate and proceed with the standard pain control regimen prescribed by your surgeon.

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?

You have been asked to take part in a research study because you are scheduled to undergo either anatomic or reverse total shoulder replacement surgery.

Narcotic (also known as opiate) medications are commonly prescribed to patients after shoulder replacement surgery. Although these medications are effective in controlling pain after surgery, they have multiple risks and side effects, including nausea, vomiting, constipation, respiratory depression, and addiction.

The purpose of this research study is to evaluate the effectiveness of a non-narcotic medication regimen in controlling pain after shoulder replacement surgery compared to

a medication regimen which includes narcotic pain medications. The narcotic medication used in this study is Percocet 5 mg/325 mg (oxycodone hydrochloride 5 mg and acetaminophen 325 mg). This medication is FDA (U.S. Food and Drug Administration) approved and is commonly used for pain control after surgical procedures. The non-narcotic medication regimen used in this study includes the following postoperative medications:

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

These non-narcotic pain medications are FDA approved. In the prescribed dose, these medications are considered safe, effective, and to be without addictive traits.

A total of people 56 people will be enrolled at Henry Ford Health System (HFHS).

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

There will be 2 groups in the study. You will be randomized into one of the study groups described below. Randomization means that the group you are assigned to will be chosen by chance, (like flipping a coin). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in group 1 (often called "Arm A"), you will receive a prescription of 60 tablets of a narcotic pain medication called Percocet to be taken every 4 to 6 hours as needed for pain after surgery. You will also receive the medications outlined below for your pain after surgery.

If you are in group 2 (often called "Arm B"), you will not receive a prescription of Percocet. You will only receive the medications outlined below for your pain after surgery.

The following medications will be prescribed to you regardless of which group you are placed in:

1. Ibuprofen (Motrin)
    a. 600 mg by mouth, every 6 hours as needed for pain for 1 month; not to exceed 3200 mg/day
2. Pregabalin (Lyrica)
    a. 75 mg by mouth every 12 hours for 2 weeks
3. Acetaminophen (Tylenol)
    a. 1,000 mg by mouth, every 8 hours as needed for pain for 1 month; not to exceed 3000 mg/day
4. Tizanidine (Zanaflex)
    a. 2 mg by mouth every 6 hours for 2 weeks
5. Dexamethasone (you will only be prescribed this medication if you are discharged from the hospital on the same day as your surgery)
    a. 4 mg by mouth every 12 hours for 4 days
6. Magnesium
    a. 200 mg by mouth every 12 hours for 2 weeks

You may choose to take no pain medication if you are not having any postoperative pain.

If you are in Group 2 and your pain is uncontrolled, you may call in for a prescription of Percocet. During normal business hours, call your surgeon at the number that has been provided to you to request this medication. Outside of normal business hours and on the weekends, call the Henry Ford West Bloomfield operator at (248) 325-1000 and request to speak with the Orthopaedic Surgery resident on call.

The details of your instructions after surgery are as follows:

During the first 10 days of your recovery period after surgery, you will respond to automated text messages asking you about your pain levels, the number of narcotic pain medications you are taking, and medication side effects. This will allow your providers to track your pain and progress after surgery.

- You will be sent a total of 5 text messages per day for 10 days: 1 in the morning, 1 in the afternoon, and 3 in the evening.
- These messages will ask you about your pain, the number of narcotic pain pills you are taking, and medication side effects you may be experiencing. You will respond to each question by texting back a number from 1 to 10.
- You will stop receiving text messages on the 11th day following your surgery.

You will see your surgeon in clinic at the standard 1-week, 6-week, 3-month, 6-month, 1-year, and 2-year intervals after surgery. During these clinic visits, you will be asked to complete questionnaires asking about your pain, shoulder function, and emotional well-being. These questionnaires will be used to measure your improvement after surgery. Your surgeon will also perform a routine clinical examination of your shoulder and evaluate your overall health at these visits. The information your surgeon records in your medical record pertaining to these visits will also be used to measure your improvement after surgery.

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

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

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

All medications used in this study are FDA approved and currently used for pain control after surgery at HFHS. Each medication carries side effects and should be taken only in the approved dosages. The researchers will try to minimize these risks by taking a thorough history of any previous use of these medication and any adverse side effects that were experienced. 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.

It is possible that you may encounter increased pain after your surgery. To avoid unnecessary discomfort, you can request additional pain medication. During normal business hours, you can request this medication by calling your surgeon at the number that has been provided to you. Outside of normal business hours and on the weekends, call the Henry Ford West Bloomfield operator at (248) 325-1000 and request to speak with the Orthopaedic Surgery resident on call.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected*?"

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

Depending on which group you are assigned, the benefits of participating in this study may include:

- Improved pain control and increased comfort after surgery.
- Decreased risk of nausea, vomiting, constipation, respiratory depression, or addiction (caused by narcotics).

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?

Participation is voluntary. The alternative is to not take part in this research study. If you decide not to participate, the pain control medications you will receive after your shoulder replacement procedure will be decided by your surgeon. These medications may include some or all of the medications used in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Data collection under this protocol shall be conducted in a way that conforms to all applicable local and national rules, regulations, and guidelines relating to the conduct of clinical research and the protection of patients.

Research records will not include your name 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 called your Medical Record Number (MRN). The researchers will maintain all research records on a secure Henry Ford Health System server. A copy of this consent form will be stored in a secure location in the Principal Investigator's locked research office. Your responses to automated text messages will be stored in a secure online database. The only information that will be entered into this database is your MRN, phone number, and date of surgery.

Your responses to the automated text messages will not be made a part of your regular medical record. Other information created or collected as a part of this study may become a part of your regular medical record. This information includes pain medications that you are prescribed as a part of this study and responses to the questionnaires you will complete at clinic visits with your surgeon.

All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. 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 at the end of this study.

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. INFORMATION ABOUT CONFIDENTIALITY AND HIPAA AUTHORIZATION

A federal regulation, known as the Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any PHI collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.
We will collect and use:

- Your existing health records.
- New health information created during this study.

- Health insurance and other billing information.

This health information may contain your medical record number and other identifying information such as your age, race, gender, and zip code. Your name will not be collected or recorded for the purpose of this study.
We may release this information to the following people:

- The Principal Investigator and his/her associates who work on or oversee the research activities.
- Henry Ford Health Systems Institutional Review Boards (IRB).
- Your insurance company or others responsible for paying your medical bills.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by federal privacy (i.e., HIPAA) regulations.
No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.
This Authorization to use and release your personal protected health information does not expire.
You do not have to sign this Authorization and may cancel it at any time. If you decide to cancel your Authorization at later date, you will not be able to continue to participate in this study. If you withdraw your permissions, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the following:

Dr. Stephanie Muh
6777 W Maple Road
West Bloomfield Township, MI 48322

By signing this document, you are authorizing the PI to use and disclose PHI collected about you for the research purposes as described above.

10. 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.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

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

Dr. Stephanie Muh or her 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. Stephanie Muh by phone at 248-661-6470 or by email at smuh1@hfhs.org. Medical treatment is available to you in case of an injury.

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.

12. 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.

13. 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.

14. 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.

15. WILL I BE PAID TO PARTICIPATE?

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

DOCUMENTATION OF CONSENT

	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 12/01/2021)	DATE: MRN: NAME:
	PROJECT TITLE: Multimodal Nonopioid Pain Protocol Following Shoulder Arthroplasty Surgery: A Prospective Randomized Controlled Trial	

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

	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 12/01/2021)	DATE: MRN: NAME:
	PROJECT TITLE: Multimodal Nonopioid Pain Protocol Following Shoulder Arthroplasty Surgery: A Prospective Randomized Controlled Trial	

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Printed Name of Person Obtaining Consent