



Consent Form for Participating in Research

Study Title: Intrathecal Morphine vs Intrathecal Morphine Combined with Clonidine for 1-2 Level Lumbar Fusion

Location: MaineHealth Maine Medical Center Bramhall Campus Version

Date: 6/29/2026

Principal Investigator: Parker H. Merrill, MD. Spectrum Healthcare Partners, Southern Anesthesiology Division.

IRB Number: STUDY00000209

Key Information

The following is a brief summary to help you decide whether to be a part of this research study. More detailed information is listed later in this form.

Summary:

- This research is being done to improve the pain therapies that we offer to patients who are having spine fusion surgery.
- If you choose to participate, you will receive one or two pain medications during surgery. You will then be asked to give honest answers about how much pain you are feeling every day for 3 days after surgery. Your participation is expected to last 72 hours after your surgery is finished.
- Risks or discomforts from this research include common things like itching, lower heart rate, and lower blood pressure during surgery. Uncommon but serious risks include allergic reactions to medications, significant sedation after surgery, and decreased breathing requiring assistance.
- You do not have to take part in this study. If you choose not to take part, you may have other options for treatment/care and your decision will not be held against you.

Why am I being asked to take part in a research study?

We are asking you to take part in this research study because you are scheduled to have a 1- or 2- level lumbar spine fusion surgery. You are also an adult above 18 years old who is able to make your own informed medical decisions.

What should I know about a research study?

- Someone (a doctor or a research coordinator who is part of the study team) will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and change your mind later.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, there is no time limit on the consent discussion.
- You'll have at least one day to decide if you would like to participate in this study.

Why is this research being done?

The purpose of this study is to try to improve the medications we give to patients to help with their pain after surgery. Many positive changes have been made over the years, but there remains room for improvement. Lumbar spine surgery allows for easy access to the intrathecal space (the fluid around the spinal cord, or CSF) where medications can be given to directly work on pain receptors in the spinal cord. We know that two medications, morphine and clonidine, can be helpful for pain relief when given into the CSF. Our hypothesis is that adding clonidine and morphine together may offer better pain control than just morphine alone. We hope this study will give us more pain-control options for patients having spine surgery.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 3 days after surgery. We will collect data from your hospital record about the amount and types of pain medication you need, as well as your pain scores. If you are discharged from the hospital in less than 3 days, you will be asked to keep track of that information from home and a member of the study team will call you so we can record that data.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?**"*

Is there any way being in this study could be bad for me?

Participating in this study comes with a small amount of additional risk compared to the standard of care (what we currently use for treatment). You could have common but minor side effects such as rashes, itchiness, low blood pressure, low heart rate, sedation, or more pain than expected. Most of these side effects are easily and routinely treated by your care team. You may also suffer from rare complications such as severe allergic reaction, difficulty breathing, or dangerous drops in blood pressure. Your anesthesia and surgical teams are watching closely and prepared to treat any reactions that may arise.

More detailed information about the risks of this study can be found under "Could being in this study be bad for me? (Detailed Risks)**"*

Will being in this study help me?

We cannot promise any benefits to you or others from your participation in this research. However, possible benefits include better pain control, reduced need for narcotic pain medications that you take in pill form, faster discharge from the hospital, and improved physical therapy participation.

What happens if I do not want to be in this research?

Being in this research study is completely optional. You can choose to participate or not to participate.

Choosing not to participate in this research study will not affect your normal care at MaineHealth.

Study Details

In addition to the information above, the following pages give more details about this study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Janelle Richard, research coordinator, 207-662-2862, janelle.richard@mainehealth.org

This research has been reviewed and approved by an Institutional Review Board (IRB).

In the event that:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

You may contact the Institutional Review Board by calling (207) 661-4474, or via email at hrpplRB@mainehealth.org

How many people will be studied?

We expect this research study will include about 70 people nationally. All of those people will be at MaineHealth.

What happens if I say yes, I want to be in this research?

You will start by going through the informed consent process with someone from our research team. They will explain the risks, benefits, and details of the study as described in this document. If you choose to sign this consent form, you will be enrolled in the study.

After enrollment, you will be randomly assigned to one of the two treatment groups. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. You will not be told which treatment you are getting. However, your study doctor will know. The experimental treatment group will receive morphine with clonidine, and the standard (control) treatment group will receive morphine without clonidine.

You will go through the normal evaluation by your surgical and anesthesia teams prior to surgery. You will arrive on the day of surgery and go through the same intake process that you would have even if you were not in the study. You will meet your anesthesia team prior

to surgery, who will go over the consent for general anesthesia. You will then proceed to surgery under general anesthesia.

While you are asleep and undergoing surgery, the research team will provide the study medication that has been randomly assigned to you (either intrathecal morphine or intrathecal morphine with clonidine). This medication will be given to you by the surgeon directly in the CSF (cerebrospinal fluid) where it is able to work on your pain centers. The anesthesia team will be monitoring closely for any changes to your heart rate and blood pressure and will administer additional medications as needed.

After surgery is complete, you will wake up from general anesthesia in the recovery room and will be monitored closely for vital signs and sedation (how groggy you are from pain medication). You will also be asked about your pain on a scale from 0 (no pain) to 10 (worst pain imaginable). Your answers to this question may prompt your team to give you additional pain medication. You may refuse additional pain medication at any time if you feel you do not need it.

After you leave PACU, you may proceed to the hospital floor where you will continue to be monitored for safety and recovery. You will be asked at regular intervals about your pain on a 0 to 10 pain scale, and you may be offered additional pain medications. You may also request or refuse pain medication at any time if you feel you need it. These pain survey questions will continue for a total of 3 days.

Once you are sufficiently recovered, your surgical team will determine when you can be discharged from the hospital. If you are discharged from the hospital earlier than 3 days after surgery, you will be given a log sheet to record pain scores and any pain medication you take at home. A member of the study team will call you to collect this data.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: Providing honest and accurate ratings of your pain symptoms at regular intervals after surgery. You may need to keep track of your pain scores and pain medication usage at home if you are discharged less than 3 days after your surgery.

What happens if I say yes but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave this research study, you may do so at any time. Choosing to leave prior to surgery will result in normal clinical care, and you will not receive the study medications. If you choose to leave the study after the surgery has been performed, you will have already received the study medications and will have the effects of these medications, but you will no longer participate in the follow-up.

If you do decide to leave the research, contact the investigator so that the investigator can address the parties involved and ensure that your removal is completed appropriately.

Will being in this research study cost anything?

You or your insurance company will not be charged for any tests or services specifically required by this research study unless the tests or services are clinically indicated or are part of your standard treatment. You will still be responsible for the cost of your usual ongoing medical care. This includes co-pays, procedures, non-study medications, and tests that your study doctor or regular doctor requires during this study as part of your usual medical care.

Could being in this study be bad for me? (Detailed Risks)

There is no medical treatment that is without risk. Participating in this study has a small amount additional of risk compared to the standard of care. Specific risks to consider include the following:

Common but minor side effects such as hypotension (low blood pressure), bradycardia (slow heart rate), itchiness, sedation, poor pain control, constipation, rash.

Other uncommon but serious side effects include severe hypotension, severe bradycardia, anaphylaxis (Allergic reaction), cardiac arrest, respiratory arrest.

Your anesthesia and surgical teams are closely monitoring you for reactions to medications and are prepared to treat the above complications with the standard of care. Please see below for relevant side effects with their severity, risk, and treatments below.

<i>SIDE EFFECT</i>	<i>SEVERITY</i>	<i>RISK</i>	<i>TREATMENT</i>
Itchiness	Mild-moderate	Common (30-60%)	Time, Medications
Sedation	Mild	Common (25%)	Monitoring
Hypotension/low blood pressure	Mild-moderate	Common (50%)	Monitoring, IV fluids, Medications
Bradycardia/slow heart rate	Mild-moderate	Uncommon (0-10%)	Monitoring, Medications
Respiratory Depression/slow breathing	Mild-Severe	Rare (<1%)	Monitoring, Medication
Allergic Reaction	Moderate-Severe	Rare (<1%)	Medication, Allergy testing

These risks are specific to intrathecal morphine and clonidine. Other pain medications carry other risks that are not described here. We are not able to predict whether the risks described here are lesser or greater than the risks associated with other pain medications.

Research Related Injuries

If you think you have been injured or become ill because of taking part in this study, tell the study doctor (Dr. Parker Merrill; 207-662-4562; parker.merrill@spectrumhcp.com) or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, MaineHealth will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911.

If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs to treat your research-related injury or illness. There are no

plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study.

Determination Date: 06/20/2023

What happens to the information collected for the research?

Efforts will be made to protect your medical records and other personal information to the extent entitled by law. However, we cannot guarantee absolute confidentiality. Records of research study participants will be stored and kept in a HIPAA compliant on-line database called REDCap. Once data collection is complete, the link between your name and other personal identifiers and your medical information will be deleted. The data will be kept for 6 years after the completion of the study before being destroyed.

The results of this study may also be used for teaching, publications, or presentation at scientific meetings.

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, other groups may request to inspect and/or copy your research and medical records for quality assurance-related data analysis, other research-related processes, or as part of administrative or operational activities. These groups include:

The Food and Drug Administration (FDA), MaineHealth, MaineHealth Institutional Review Board (IRB), or federal research oversight agencies.

Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The monitors, auditors, the IRB, the Food and Drug Administration (FDA) will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on <https://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 study's results. You can search this website at any time.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA Authorization section.

Additional Considerations

Can I be removed from the research without my permission?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include: allergic reactions to study medications, changes to your surgical plan, significant changes to your medical history, or other unanticipated circumstances that would require your removal from the study.

New Findings

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

What else do I need to know?

Payment for Participation

If you agree to take part in this research study, you will be paid for completing the following visits/activities:

- Pain scores, pain medication usage for 3 days following surgery - \$40

All study activities must be completed to receive payment; payment will occur within 1 week of the end of your participation. You can also choose not to receive payment.

If you choose to receive payments, you will be asked to complete a W-9 form one time prior to receiving the payments. This form will ask for your social security number, name, and legal address. If your total payments are more than \$2000.00 each tax year, you may be sent a 1099-MISC form for your taxes. The amount that requires this form to be sent changes each tax year and is always more than \$2000.00. MaineHealth will not take taxes out of any compensation you receive as part of this research study. If you have any questions, the research staff can assist you.

You can receive your payments by a paper check mailed to you by MaineHealth. Alternatively, MaineHealth has contracted with a company that will process these payments on our behalf. If you choose this method, the payments will be made via a reloadable prepaid card or direct bank deposit. The company may receive your name, date of birth, address, gender, guardianship status, participant identifier, social security number, and email to process these payments. If you select the direct bank deposit option, you will also need to provide your bank account information to the company. You will receive a separate handout with this consent form that explains how the payments will be made.

Please check the appropriate box:

- ☐ You would like to be paid for your participation in this study and understand that if you are paid more than \$2000.00 in a tax year, your payments may be reported to the IRS and you may be required to pay taxes on this money.
- ☐ You do not wish to be paid for your participation in this study.

Please initial here: _____

- Instead of being in this research study, you may choose to proceed with the current standard of care for pain control. This may include medications being studied in this trial, and may also include other IV and oral pain medications at the discretion of the anesthesia and surgery team. The important risks and possible benefits of the current standard for pain control are similar to those discussed in this study, however you may receive different medications for pain that have different risks of allergic or adverse reactions. We cannot predict whether your risk of these reactions would be greater or lesser than if you had participated in this study. We also cannot predict if you would have better or worse pain control.
- Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for

others. It is the policy of MaineHealth not to provide financial compensation should this occur. Determination Date: 10/3/2016

Signature Block for Capable Adult Consent

Your signature documents your permission to take part in this research.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date and Time

Printed name of person obtaining consent

A signed copy of this document must be provided to the participant.

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personally identifiable information may include your name, address, phone number, or social security number.

What health information may be used and for what purpose(s)?

The health information we may collect from you and use or disclose for this research includes:

- Your name, email address, medical record number, and treatment dates
- Demographic information: sex, age, race, and ethnicity
- Results of physical examinations and vital signs (heart rate, blood pressure, breathing rate, oxygen levels)
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition
- Health-related diaries and questionnaires
- Records about study medications, drugs, and treatments
- Your responses to medications and treatments (pain scores, sedation [sleepiness vs. awakesness] scores, side effects)
- Billing information
- Sensitive Information: Substance use history, including opioid or other narcotic medications

Optional and Future Research

Sometimes, Researchers need extra permission to use your information for optional parts of the study or future research. If you agree to give this permission, add your initials below.

_____(initials) I give permission to also use the above information for future research regarding intrathecal morphine or intrathecal clonidine.

Who may have and use my health information?

Once we have the health information listed above, we may share some of this information with offices or entities outside of MaineHealth and its clinical partners (or affiliates). A list of these entities is included below.

Any research information shared with outside entities will not contain your name, address, phone number, social security number, or any other personal identifier unless disclosure of the identifier is necessary for review by these entities or is required by law or MaineHealth policy.

If you sign this form, you give permission for the following people and groups to receive, use, have and disclose the personal health information described in this form for this research study:

- Dr. Parker Merrill, anesthesiologists and neurosurgeons and staff at MaineHealth involved in the research study
- Other MaineHealth research centers and MaineHealth contractors who are also working on the study.
- Members and staff of the Institutional Review Board, and other groups or persons who help oversee the safety of the research;
- Study monitors and auditors who make sure that the study is being done properly.
- Government agencies and public health authorities, such as the US Office of Research Integrity, the US Office for Human Research Protections, the US Food and Drug Administration (FDA) and the US Department of Health and Human Services (DHHS).

What could happen if I agree to this use or disclosure of my health information?

- If you agree to this use or disclosure, your information might be shared with people or organizations who are not subject to federal privacy laws (the laws that protect the privacy of your personal health information). If this happens, the Researchers cannot guarantee that your personal health information will be protected by federal privacy laws.
- Once information that could be used to identify you has been removed (ex. Name, address, phone number), the information that remains is no longer protected by this Authorization (agreement). Researchers may then give your de-identified (not connected to your identity) information to others, including for other research reasons.
- The Researchers have agreed that no publication or presentation of the research will reveal your identity without separate specific written permission and authorization (agreement) (even if you revoke (take back) this Authorization (agreement)).

What rights do I have?

- You can choose not to sign this Authorization (agreement). If you do not sign this authorization, you cannot participate in this research study.
- You have the right to your normal healthcare and related benefits without signing this authorization (agreement). If you choose not to sign this authorization, your healthcare and related benefits outside the study will not be affected.
- You can change your mind and cancel this agreement at any time without penalty. To do so, you must revoke authorization in writing by contacting Janelle Richard, janelle.richard@mainehealth.org, Department of Anesthesiology, 22 Bramhall St., Portland, ME 04102
- If you choose to cancel this agreement, you may not be allowed to take part in the research and may stop receiving research-related treatment. Also, any information collected about you before canceling this agreement will stay in the study as necessary to preserve the quality of the research study.

What else should I know?

- You will be given a copy of this agreement after signing it.

- Determination Date:
9/28/2026
- During the research, you may not be allowed to see or copy the records described in this form. However, you will be able to see and copy the information upon completing the research in accordance with MaineHealth policy.
 - A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

When does this Authorization (permission) expire?

This authorization has no expiration date. It will expire when the permission is no longer needed by the entities listed above for the reasons listed above.

HIPAA Authorization for Self

Your signature documents your permission to use or disclose your personal health information as described in this document.

Signature of participant

Date

Printed name of participant