UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Ultrasound-Guided Genicular Nerve Block for Knee Pain in the Emergency Department: A Randomized Controlled Trial
Principal Investigator:	Michael Shalaby, MD 267-624-4394
Emergency Contact:	Michael Shalaby, MD 267-624-4394
Sponsor	N/A

Research Study Summary for Potential Participants

You are invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and the risks of participation. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to compare two treatments for knee pain not related to acute traumatic injury or infection.

If you agree to join the study, you will be asked to complete the following research procedures: You will be randomized to receive either a **genicular nerve block** performed with anesthetic (injection of numbing medication) or **conventional pain medication** (pills, topical medication, or intravenous medication).

The genicular block involves the injection of anesthetic around three nerves in your knee which are responsible for you feeling knee pain. When the numbing medication spreads to the nerves, it will anesthetize them (cause them to feel numb). We take safety precautions, which include cleaning your knee with a cleaning solution prior to performing the procedure and using the ultrasound machine to see the important parts of your knee to know where to inject the medication. We also will monitor your heart rate, blood pressure, and breathing during and after the procedure.

The alternative to receiving the genicular block is to receive normal care with oral, topical, and intravenous medications for pain. If you are selected to receive the genicular nerve block but do not achieve adequate pain control after the block, you would be eligible to receive other pain-relieving medications, as needed.

Regardless of the treatment group to which you are assigned, when you are discharged from the ED, you will be asked to rate your pain and complete a brief survey. The next day (approximately 24 to 36 hours after the procedure) you will be called to ask about your pain levels and how long the numbing medication lasted after the injection. We expect this survey to take less than 5 minutes to complete.

Your participation in this study will last until the phone call is complete approximately 24 to 36 hours after treatment.

The potential benefit of receiving the genicular block compared to conventional pain medications is improvement in or resolution of your knee pain. Some patients have reported complete pain relief for more than 24 hours after the injection and improvement in their pain for weeks. The most common risks of participation are injection site pain. Rarer risks include infection, high or low blood pressure, fast or slow heart rate, confusion, seizures, or cardiac arrest.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participating at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are invited to participate in a research study because you are having knee pain and your pain may improve after receiving a genicular nerve block.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form. You will receive a copy of this consent form.

What is the purpose of this research study?

The purpose of this study is to compare two treatments for knee pain. Compared to normal pain medication which patients would otherwise receive, this research study will investigate whether the genicular nerve block can provide better pain control for patients with moderate or severe knee pain.

How long will I be in the study?

Your enrollment in the study will last for 24 to 36 hours and will end with a short survey detailing your pain levels over the previous 24 to 36 hours. We will be recruiting patients

for this study for approximately 12 months. We plan to recruit approximately 34 patients for this study, all throughout the various emergency departments at the University of Pennsylvania hospitals.

What am I being asked to do?

You are being asked to undergo a genicular nerve block with a combination of anesthetic (also called numbing medication) and steroid (bupivacaine 0.5% and dexamethasone) or receive standard pain medications (oral, topical, or intravenous medications). The anesthetic is determined by your "ideal body weight," which will be calculated before injection. The steroid (dexamethasone 4 mg) is included to make the pain-relieving effects of the anesthetic last longer. Steroids are often included when performing nerve blocks, including the genicular nerve block, and have been shown to make the effect of anesthetic last longer. Before receiving either treatment (standard pain medications or the genicular block), you will be asked to rate your pain scale of 0-10. You will then be asked to rate your pain again prior to discharge from the ED and complete a brief (less than 5 minutes survey) after you receive the treatment. Approximately 24 to 36 hours after receiving the treatment, you will receive a phone call from a member of the study team to ask about your levels of pain and discomfort since receiving treatment.

What are the possible risks or discomforts?

The most common discomfort is from the needle passing through your skin and muscles of your knee, which is similar to a blood draw or an intravenous (IV) line being placed. To minimize discomfort, we use thin sharp needles. These needles are similar in size to the needles with which you would receive numbing medication for a dental procedure or to repair a cut on the skin (usually 20- to 22-gauge, 1.5 inches long). However, the needles may be longer (up to 3.5 inches) depending on how much distance they must travel under the skin to reach the injection site. We will use the shortest needle possible to safely deposit the numbing medication at the correct location. You may elect to decline participation if you are uncomfortable with the size of the needle.

There is also a rare chance of suffering from a skin infection from having a needle inserted through your skin. However, like when having an IV line placed, we thoroughly clean your skin with disinfectant prior to performing the injection. For each injection, we also use a new sterile needle to further minimize the risk of infection. There are also extremely rare (<1/10,000) side effects which can include fast or slow heart rate, high or low blood pressure, confusion, seizures, or death. This is called local anesthetic systemic toxicity, and it usually occurs when anesthetic is accidentally injected directly into a blood vessel. Theoretically, this may be of lower risk for the genicular block because there are no major blood vessels in the area where we are injecting. To prevent this, we always use an ultrasound machine while performing the genicular nerve block, which can show us exactly where blood vessels are so they can be avoided. We also aspirate (pull backwards on) the syringe before injecting. If no blood comes up the syringe, then it means the needle is not in a blood vessel. We also use a safe amount of anesthetic based on your ideal body weight (which is not always your actual body weight), so that we never accidentally give you too much medication. Also,

we inject the anesthetic very slowly, so if your body has a reaction to the medication, we can monitor your heart rate and blood pressure while performing the procedure. If you begin to feel strange, such as tingling in or around your mouth or other body parts, confusion, disorientation, or dizziness, please tell us immediately and we can stop the procedure. Overall, major complications of this procedure are not only extremely rare, but we also take many steps to avoid them.
If one of these rare side effects does occur, we have the medicines and know the procedures to reverse them. If local anesthetic systemic toxicity occurs, we have medicines in the emergency department to reverse it, including a medicine called intralipid which we inject into your blood vessels which prevents the anesthetic medication from causing further problems in your body. We also have antiseizure medications. If you are injured or feel any dizziness, confusion, tingling sensation, palpitations, or difficulty breathing, please inform your physician who performed the genicular nerve block immediately.

Reproductive risks
Not applicable.

Reproductive Risks for studies involving MRIs
Not applicable.

Risks of Genetic Testing
Not applicable.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
The possible benefits of this study include improved knee pain and lower opioid use, and even a potentially shorter ED stay. However, you may not get any benefit from being in this research study.

What other choices do I have if I do not participate?
If you choose not to participate in this study, you can still be treated with the pain medications which you would normally receive for your knee pain in the ED.

Will I be paid for being in this study?
No.

Will I have to pay for anything?
The cost of the genicular nerve block and the medications are already covered in this study, and you will not be responsible for paying anything extra for receiving the

procedure. You are still responsible for any deductibles or applicable co-pays for any testing or treatments that are performed during your visit in the emergency department. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

What happens if I am injured from being in the study?

If you are injured as a result of this study, please inform your treating physician and contact Michael Shalaby at Michael.shalaby@pennmedicine.upenn.edu to report your injury. Injuries incurred as a side effect of this study, as listed above in the "What are the possible risks or discomforts?" section, are treated immediately. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have received the genicular nerve block, have answered the survey given at approximately 24 to 36 hours after the injection, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information

from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

The confidentiality of your information will be protected in the following way during the study: all information will be coded, stored in a secured, password-protected program called REDcap, access to which will only be available to the members of the study.

Infectious Disease Testing and Reporting
Not applicable.

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

What may happen to my information collected on this study?
Future Use of Data
Your information will be de-identified prior to storage for future use. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study. If you change your mind, we will not be able to destroy or withdraw your information that was shared because all identifiers would have already been removed.

Electronic Medical Record and Release of Study Related Information
What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to

obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR, your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information is not shared through HIEs, please call 215-662-4484.

Will I, as a participant, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM). All data collected in this study will be data which you will provide, such as how you are feeling after receiving the genicular block.

Will I receive the results of research testing that may be relevant to my health?

Results that may be relevant to your healthcare may be released to you. Any results relevant to your healthcare will be released in the EMR through Penn Medicine's patient portal.

What information about me may be collected, used or shared with others?

Your phone number will be shared with the research assistants so they can call you approximately 24 to 36 hours after you receive the genicular block to administer a short survey about your pain levels. Your age in years, sex assigned at birth, your gender, your personal medical history, and results from physical examinations and tests (such as X-rays) will be used for the purposes of this study. However, this information will not

be shared in a manner which will make you identifiable. Your social security number, home address, and date of birth will not be collected or shared with others.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done correctly
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

Nobody outside of Penn Medicine will receive any of your information. No entities outside of the U.S. Office of Human Research (OHRP) will have oversight of this research.

<u>Oversight organizations</u>

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

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

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Financial Interest Disclosure

No outside funding is being used to support this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you agree to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Participant **[print]**	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date

For use with Non-English Speaking participants / LARs utilizing a short-form process:

_____	_____	_____
Name of Witness (Please Print)	Signature of Witness	Date
_____	_____	_____
Name of Interpreter (Please Print) *(When available)*	Signature of Interpreter	Date