# You Are Being Asked to Be in a Research Study

**Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer if the administration of the Medrol Dose Pak will lead to decreased pain, nausea, and opioid consumption in the weeks following total knee replacement. If you agree to be in the study you will be one of 101 people who are being studied at Emory.

## Why is this study being done?

This study is being done to answer the question: There are different steroid formulations available, and in this particular study, we are evaluating the effects of administering a Medrol Dose Pak, which is a commonly available glucocorticoid taper which is a steroid and is administered over a short period of time after surgery. Steroids are medications that are used to reduce inflammation, pain, and swelling among users. Glucocorticoids are a type of steroid that have the same functions since they also reduce inflammation, pain, and swelling among users. Our hypothesis is that the administration of the Medrol Dose Pak will lead to decreased pain, nausea, and opioid consumption in the weeks following total knee replacement. You are being asked to be in this research study because this study is designed to learn about the effects of steroids on your surgery type and to benefit patients like you in the future.

## Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

## What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 7 days along with regular 3 month post-operative follow up appointment. The researchers will ask you to do the following: This study will be a randomized trial consisting of patients who are treated for knee arthritis. Patients will be randomly assigned to one of two groups at the time of surgery. The experimental group will receive medical management with Medrol dose packs and all other forms of standard care, while the control group will only receive standard care. Patients will be randomly allocated to one of the two groups. None of these procedures will be paid for by the study.

**How is this study going to help you?**

If you are in the study, you will be helping the researchers answer the study question. Furthermore, by identifying the outcomes with the administration of steroids peri-operatively, the authors can help educate physicians and patients on the benefits of this specific treatment. Low-dose, short-term corticosteroid regimens to be safe and effective for reducing postoperative pain without an increase in complications. Also, the utilization of corticosteroids in combination with opioids postoperatively has also been shown to decrease opioid consumption and the incidence of opioid-related postoperative side effects.

**What are the risks or discomforts you should know about before deciding?**

The study will take time. As stated above, there is no literature to support the notion that low dose steroids pose any danger. The time of surgery is associated with any toxicity or complications. Even high dose perioperative steroids showed no complications in surgical site healing, infections, or osteonecrosis at 1 year [4]. Furthermore, intraoperative intravenous (IV) dexamethasone remains standard of care at Emory. The addition of a methylprednisolone taper course poses minimal additional risk to the patient. Nevertheless, the absence of proof does not prove absence of risk. There is a theoretical risk of side effects from the steroids received at the time of surgery. Short-term steroids are generally safe, but there is a slight risk of short term and Long-term side effects. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Hyperglycemia
- Infection
- Mood Changes
- Osteonecrosis of the hip
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

**Alternatives to Joining This Study**

Since this is a treatment study, the alternative is not to participate.

**Costs**

Emory will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which Emory does not pay. Emory will not pay for your regular medical care.

There is more information in the "Costs" section further below.

**What Should You Do Next?**

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

**Emory University**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Methylprednisolone Taper after Total Knee Replacement: A Prospective Randomized Trial

**IRB #:** STUDY00005985

**Principal Investigator:** [redacted] Emory Department of Orthopaedics

**Introduction**

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you.
- Listen to the study doctor or study staff explain the study to you.
- Ask questions about anything that is not clear.

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal 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.

**What is the purpose of this study?**

Total knee replacement surgery is a commonly performed and widely successful surgery to improve mobility and decrease pain in patients suffering from severe knee arthritis. However, in the immediate period after knee replacement, patients often experience significant pain and nausea, which can limit early recovery after surgery. Steroids are anti-inflammatory drugs that can reduce pain and swelling by blocking the inflammatory process, and have already shown promise in various surgical settings, including after knee replacement. There are different steroid formulations available, and in this particular study, we are evaluating the effects of administering a Medrol Dose Pak, which is a commonly available steroid taper that is administered over a short period of time after surgery. Our hypothesis is that the administration of the Medrol Dose Pak will lead to decreased pain, nausea, and opioid consumption in the weeks following total knee replacement.

**What will you be asked to do?**

The researchers will ask you to do the following: This study will be a randomized trial consisting of patients who are treated for knee arthritis. Patients will be randomly assigned to one of two groups at the time of surgery. The experimental group will receive medical management with Medrol dose packs and all other forms of standard care, while the control group will only receive standard care. Patients will be randomly allocated

to one of the two groups. No groups will be blinded to the treatment or control groups, i.e. you will know if you are in the group receiving the medications or not. After your surgery, you will receive a prescription which you will fill at your pharmacy. You will be asked to take that medication as instructed on the medication packet. You will be asked to fill in a pain journal during the first 7 days after surgery. You will need to follow up with your orthopaedic surgeon for your regular post-operative follow up appointment at 3-months. These appointments are meant to follow up healing status after your surgery and to assess the progression of healing at your surgery site. These are normal follow-up appointments after the type of surgery you received. None of these procedures will be paid for by the study.

**How will your study drug be provided**?

One dose of medication will be provided at the time of surgery, and the medication will be given intravenously which is the standard care at Emory University. In addition to the intravenous dose of the steroid, a prescription for medication will be provided for you that you will take at home on your discharge from the hospital. This medicine is in a packet of pills that you will take orally as directed on the box. You will take this packet of pills for a total of 6 days after surgery.

If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

> Note: The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

**Who owns your study data and samples?**

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, all collected data up to the point of withdrawal will be retained and included in the analysis, unless the participant requests that their data be destroyed. The decision to withdraw a participant from the study will be made by the principal investigator, in consultation with the research team and the IRB, as needed.

**What are the possible risks and discomforts?**

There may be side effects from the study drug or procedures that are not known at this time. However, there is a theoretical risk of side effects from the steroid received at the time of surgery.

The less common risks and discomforts expected in this study are hyperglycemia, infection, and mood changes.
Rare but possible risks include osteonecrosis of the hip.

Also, there is a possibility of a breach of confidentiality.

**If it is biologically possible for you to become pregnant**: to protect against possible side effects of the study drug, people who are pregnant may not take part in this study. If you take the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

**Will you benefit from the study?**

This study is designed to learn more about the efficacy of Medrol dose-paks. Study results may be used to help others in the future. If you are in the study, you will be helping the researchers answer the study question. Furthermore, by identifying the outcomes with the administration of steroid peri-operatively, the authors can help educate physicians and patients on the benefits of this specific treatment. Low-dose, short-term corticosteroid regimens to be safe and effective for reducing postoperative pain without an increase in complications. Also, the utilization of corticosteroids in combination with opioids postoperatively has also been shown to decrease opioid consumption and the incidence of opioid-related postoperative side effects.

**Will you be paid for your time and effort?**

You will get $40 for participation in the study. You may be asked to fill out a tax form with your Social Security or Taxpayer Identification Number depending on the amount and method of payment. If your payment will be sent to your house in the mail and could be seen by others in your household you can choose not to be compensated. You can decline payment if you are concerned about confidentiality, or you can talk to the study team if there are other ways to be compensated.

We are planning to provide compensation in the amount of $40 to you by direct deposit. a personal payment card. We issue this to you free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if direct deposit ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your

household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.

**What are your other options?**

If you choose not to join this study, you can get care outside of this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

**How will your private information be protected?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

**Storing and Sharing your Information**

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee the anonymity of your personal data.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee the anonymity of your personal data.

All data will be kept in encrypted files on password protected devices and when possible, on Emory Box and accessible only by Institutional Review Board (IRB) approved study personnel. Each file and folder are password encrypted and personnel must login via passwords to gain access to the folders. When data collection is complete, all identifiers will be removed from the data set prior to analysis. If there is a data breach the study personnel will report this immediately to the IRB.

**Medical Record**

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

**In Case of Injury**

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory does not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

**Costs**

Emory will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which Emory does not pay. Emory will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that is not covered. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

**Withdrawal from the Study**

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

## Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for this study.

**PHI that Will be Used/Disclosed:**
The PHI that we will use or disclose for this study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study

**Purposes for Which Your PHI Will be Used/Disclosed:**
We will use and disclose your PHI for the conduct and oversight of the research study. We will use and disclose your PHI to provide you with study related treatment and for payment for such treatment. We will also use and disclose your PHI to conduct normal business operations. We may disclose your PHI to other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

**Use and Disclosure of Your Information That is Required by Law**:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

**Authorization to Use PHI is Required to Participate**:
By signing this form, you give us permission to use and disclose your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

**People Who will Use/Disclose Your PHI:**
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will disclose your PHI to other people and groups to help conduct the study or to provide oversight for the study.

The following people and groups will use your PHI to make sure the research is done correctly and safely:

- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Public health agencies
- Research monitors and reviewer

- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be disclosed with that new institution and their oversight offices. PHI will be disclosed securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

**Expiration of Your Authorization**
Your HIPAA authorization will expire when this research study ends.

**Revoking Your Authorization**
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact Dr. [redacted], Atlanta, GA 30329.

At that point, we will not collect any more of your PHI. We may use or disclose the PHI already collected so we can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

**Other Items You Should Know about Your Privacy**
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your PHI to people who are not covered by the Privacy Rules, then your PHI won't be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your PHI to others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed to other people or organizations for purposes besides this study.

**Contact Information**

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

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***TO BE FILLED OUT BY SUBJECT ONLY***

**Print** your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

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**Name of Subject**

_____ _____

**Signature of Subject (18 or older and able to consent)** **Date** **Time**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

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**Name of Person Conducting Informed Consent Discussion**

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**Signature of Person Conducting Informed Consent Discussion** **Date** **Time**