WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Department/Section of Anesthesiology and
Neurobiology and Anatomy

PAIN AND FUNCTION AFTER ORTHOPEDIC SURGERY

Informed Consent Form to Participate in Research
James C. Eisenach, M.D. Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are having a unicompartmental knee replacement, a total knee replacement or a total hip replacement. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to observe whether chronic pain after surgery is caused by responses that your body has to the surgical event and whether things in your environment have a bearing on the pain you may experience after your surgery.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 75 people at Wake Forest Baptist Health will be studied.

WHAT IS INVOLVED IN THE STUDY?

Prior to Surgery

Once you have agreed to participate, we will talk to you about your surgery, your pain and how you think about your pain and recovery after your surgery. We will show you a short slide presentation on a computer. You will be asked to fill out three questionnaires before the slide presentation and one questionnaire after we talk and show you the slide presentation. We will also ask you about your medical history and the medications that you are taking. We will give you some materials to take home and read. We will also arrange a time to call you in one week to talk about the materials that you have been asked to read.

Phone Follow-Up

One week later, we will call you at the time we pre-arranged in our first meeting. We will talk to you about the material that we asked you to read and we will ask you to complete the short questionnaire that we have provided in your take home packet at this time. We will also ask that you return the questionnaire to us in the envelope that we have provided. We will ask you to complete a total of 5 questionnaires before your surgery.

Day of Surgery

We will ask you to rate your pain before you go to surgery. We will also collect information from your medical record including the type of surgery you are having, the medications that you are talking, the type of anesthesia that you have for your surgery, the type of pain you have, the amount of pain medication that you use after your surgery and the number of days you are in the hospital after your surgery as well as any other significant events that happen during your hospital stay.

Hospital Discharge

When you are discharged from the hospital you will be given a notebook with the questionnaires and instructed how to complete the questionnaires. We will ask you to complete the same 3 questionnaires for 4 weeks after you are discharged from the hospital for a total of 114 questionnaires.

We will ask you to complete the questionnaires as follows:

A. From discharge to day 14: You will complete the questionnaires in the morning and in the evening.

B. Once daily (day 15 to day 28): You will be asked to complete the questionnaires at the end of you day, just prior to going to sleep. We will provide you with a postage-paid, addressed envelope to return the questionnaires to us. The questionnaires will not contain any information that can identify you. They will have only your study identification number on them.

C. Once weekly (day 29 to day 85): You will be called at your home and participate in a brief interview.

D. Once monthly (day 86 to day 168): You will be called at your home and participate in a brief interview once each month.

Each of the assessments will only require about 5 to 10 minutes to complete.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 months.

You can stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

What About My Health Information?

In this research study, any information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** type of surgery you are having, type of anesthesia you received, medications you received while in the hospital and the amount of pain you are having before and after your surgery.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it might no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study will be kept in the research records for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified] [Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. James Eisenach that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

James C. Eisenach, MD
Department of Anesthesiology
Wake Forest School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

This authorization is valid for six years or five years after the completion of the study, whichever is longer.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $100 if you complete all the scheduled study visits and requirements. If you withdraw for any reason from the study before completion you will be paid for each complete study visit as follows:
Completing preoperative questionnaires: $25
Completing first 28 day questionnaires: $25
Study completion: $50
To receive payment you must return all study related materials.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance

Management, at (336) 716-3467.

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. James C. Eisenach at (336) 716-4498 during regular business hours and after hours you may page the study coordinator by calling (336) 806-9496.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. James C. Eisenach at (336) 716-4498 during regular business hours and after hours you may page the study coordinator by calling (336) 806-9496.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed)	
Subject Signature	Date/Time
Person Obtaining Consent	Date/Time