Version Date: 03/10/2015

Northwestern University
Department of Orthopaedic Surgery

Consent Form and HIPAA Authorization for Research

PROTOCOL TITLE: Stability of the Medial Pivot Total Knee Prosthesis

PRINCIPAL INVESTIGATOR: Dr. David Manning, MD

SUPPORTED BY: Northwestern University

Introduction
You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

Conflict of Interest Disclosure
The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who may also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

What is the reason for doing this study?
You are being asked to participate because you will be undergoing a total knee replacement as a patient of Dr. David Manning or Dr. Matthew Beal.

This study aims to compare the function of knee replacements with two different types of prosthesis designs. The two designs are called the 1) posterior stabilized design or the 2) medial pivot design. Both devices are routinely used in knee replacement surgery. We are interested in studying them because they are different in how they stabilize the knee joint.

The posterior stabilized design uses a cam-and-post mechanism, in which one piece of the prosthesis has a plastic post that fits into a slot in the other piece of the prosthesis. The medial pivot design, on the other hand, uses a ball-and-socket mechanism. While both designs are known to function very well, it is not known yet if one design works better than the other. This study aims to help answer that question.

How many people will take part in this study?
The study investigators hope to enroll 100 subjects at NU.

What will you do if you choose to be in this study?
If you consent to participate, you will be requested to undergo the following steps:

1) You will be randomized into either one of the two groups below prior to surgery. Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group:
   - Knee replacement with Medacta GMK Sphere (medial pivot design with ball and socket)
     OR
   - Knee replacement with Medacta GMK PS (posterior stabilized design with cam and post)
2) You will also be asked to fill out the Oxford Knee Score, Knee Society Score, VR-12, and the Forgotten Joint Score (FJS) for the knee questionnaires immediately after surgery and at all the subsequent visits i.e. 6 weeks after surgery, 3 months after surgery, 6 months after surgery, 12 months after surgery, and 2 years after surgery to assess the long term outcomes such as pain, physical function, mobility, etc. after THA. You will complete these surveys at your regular follow up visits with your surgeon or over the phone; you will not need to make any extra trips because you are enrolled in this study.
3) At 3-6 months after surgery, you will be asked to undergo an examination by one of your surgeon's colleagues to determine the stability of your knee replacement. This will include checking by hand and checking with a special measuring device called the KT1000. The KT1000 is a specialized ruler that can be held against your leg to measure relative motion between your thigh bone and your shin bone. You will also be asked to perform a get-up-and-go test at this time. This test includes standing from a chair while your doctor observes. As above, these tests will be performed at your regular follow up visit with your surgeon and will not require any extra clinic visits.

The total duration of follow up for this study will be 2 years.

What are some of the possible risks and discomforts?

There are several potential risks and discomforts involved in this study. One is the inconvenience of completing questionnaires. Another is feeling pain during stability testing. Your level of pain will be assessed prior to stability testing, and if the degree of pain is felt to be too great by you or your examiner, the test will be done at your next visit. An additional risk is sustaining a fall during the get-up-and-go test. We will ask about your usual level of function to determine if it is safe to perform the get up and go test. Any canes/walkers that you normally use will be made available.

One additional possible risk related to your participation in this study is the loss of privacy. To reduce these risks, all of the information collected will be coded (you will be assigned a study number and all data will be linked to that number and not the patient's name) and stored in a password-protected file on a password-protected computer. Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Please note that both knee prostheses included in this study are in common use by orthopaedic surgeons today. Both designs are known to function very well for knee replacement surgery and have been approved for use by all relevant regulatory bodies. There is no evidence that either of these designs works better for any particular type of patient or type of knee problem; as such, each design has individually been deemed a suitable choice for your knee replacement by your

surgeon. Therefore, there are no additional risks involved in the use of these implants for this study.

What are the Possible Benefits for Me or Others?
You are not likely to have any direct benefit from being in this research study.
Taking part in this study may help future patients that undergo knee replacement surgery.

What other procedures or courses of treatment might be available to me?
You do not have to take part in this research study. You can still have the procedure regardless of whether you consent to participate in the study. The type of prosthesis used, along with other alternatives, will be discussed with your surgeon. If you do not take part in this study, the care or treatment you receive at this hospital or any other hospital will not be affected.

Are there any financial costs to being in this study*?*
The cost of your conventional medical care will be billed to you or to your health insurance company in the usual way, including the prosthesis, surgery and usual clinic visits. However, some health insurance plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

Will I receive payment for participation in this study?
You will not be paid for your participation in this study.

What should I do if I am injured as a result of being in this study?
If you become ill or get an injury or illness as a result of study devices or procedures, you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If I have questions or concerns about this research study, whom can I call?
You can call us with your questions or concerns.

If you have any illness or injury during your time on this study, you should call us promptly.

Dr. David Manning is the person in charge of this research study. You can call him at (312) 695-2071 during Monday through Friday, 9 am to 5 pm.

What are my rights as a research subject?
If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as questionnaires

The following groups of people may give the researchers information about you:

- All current and previous health care providers, including but not limited to Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]**.**

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
- Clinical affiliates, including but not limited to the Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Hospital (NMH), and Northwestern Memorial Physicians Group (NMPG)

- Study monitors and auditors who make sure that the study is being done properly

- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS)

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

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

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:
- Dr. David Manning, MD
- Northwestern University Department of Orthopaedic Surgery
- 676 N. St. Clair, Suite 1350
- Chicago, IL 60611
- Unless you revoke your consent, it will not expire.

Version Date: 03/10/2015

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above. A copy of the consent form will be provided to me after I sign it.

A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

_____	_____
Subject's Name (printed) and Signature	Date
_____	_____
Name (printed) and Signature of Person Obtaining Consent	Date