**HOSPITAL FOR SPECIAL SURGERY**
535 East 70th Street
New York, NY 10021

# INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Magnetic Resonance Imaging as a Biomarker For Adverse Local Tissue Reaction In Individuals With Hip Arthroplasty (Retrieval Arm)

PROTOCOL NO.:

SPONSOR: National Institutes of Health (NIH)

INVESTIGATOR: Hollis Potter MD

SITE(S): Hospital for Special Surgery / Division of MRI, Adult Reconstruction & Joint Replacement Division, Department of Pathology, Epidemiology & Biostatistics Core Facility

STUDY-RELATED PHONE NUMBER(S): 212-606-1886

IRB #: 13084

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you currently undergoing revision total hip replacement surgery.

**You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care**.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

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.

## 1. WHY IS THIS STUDY BEING DONE?

The purpose of the study is to create a method to detect and predict factors that could lead to success or failure of total hip replacement surgery. Your overall participation will involve a total of **1** visit.

## 2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, one of the following routine and/or experimental procedures (Retrieval Analysis) will be performed:

For this study, we will: 1) Ask you to have a physical examination with your surgeon; 2) Collect a blood sample preoperative or intraoperative (~1 teaspoon); 3) Ask you to fill out a questionnaire (~10 mins); 4) Acquire X-Ray images (~½ hr); 5) Acquire MRI images (~1 hr) to include a research sequence for seeing tissues near your total hip replacement; 6) Have your surgeon perform a visual evaluation of the soft tissues around your total hip replacement when the revision surgery is performed; 7) Acquire tissue samples near your implant during the revision surgery for pathologic evaluation; 8) Perform a detailed wear analysis of your original hip implant following the revision surgery.

| Study Visit # | Physical Exam | Blood Draw | Surveys / Questionnaires | X-Rays | MRIs | Surgery | Surgical Damage Grading | Tissue Sample Pathology | Implant Wear Analysis |
|---|---|---|---|---|---|---|---|---|---|
| #1 (Pre-Op Visit) | SOC | X | X | SOC | X* | SOC | X | SOC | X |

**Those procedures marked with an "X" will be covered by the study.**
**Procedures that are marked "SOC" will be billed to you and/or your insurance**

***Note: If your surgeon has <u>NOT</u> requested an MRI as part of your clinical standard-of-care, then funding from the National Institutes of Health (NIH) will cover the costs of the MRI exam.**

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care ordered by your physician, that is, care that you would receive even if you were not in this study. At the time of the enrollment, if an MRI scan has not been acquired as a SOC procedure, then one will be scheduled by a research assistant prior to surgery, and the cost of the MRI scan will be covered by the study.

A portion of your tissue sample data will be sent to the Medical College of Wisconsin. The tissue sample will be de-identified with a unique study code (e.g. THA001) which will only be known to and secured by the study organizers at HSS.

Your participation will involve a total of **<u>1 study visit</u>** which is expected to last 2 hours.

A total of 225 subjects will participate in this portion of the study at HSS.

You qualify for this Retrieval Analysis study if you:

1. Have a total hip replacement with a ceramic component undergoing revision for any reason, including recurrent dislocation.

2. Have a metal-on-polyethylene total hip replacement and have repeated dislocation, or
3. Have a metal-on-polyethylene total hip replacement greater than 1 year old, or
4. Have an infected total hip replacement (any surface bearing)

You do not qualify for this study if you:

1. Have occupational exposure to cobalt or chromium
2. Presence of MOM or recalled implant
3. Have had a prior revision of your total hip
4. Standard contra-indications to MRI

**3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?**

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are:

The risks of blood drawing include mild pain, bruising, and very rarely infection at the place of the needle insertion.

Magnetic Resonance Imaging: The potential risks of MRI are minimal. There is no ionizing radiation involved with MR imaging. All imaging protocols and imaging coils used in this study are FDA approved, are validated for safety and are in current clinical use at the Hospital for Special Surgery. MRI is generally a well-tolerated procedure and you will be fully screened for MR safety before any imaging is started. In particular, you will be asked if you have any of the following: aneurysm clips on a cerebral artery, a deep brain stimulator, cardiac pace maker, wires or defibrillator, inner ear or cochlear implants, hearing aid, infusion pump or metal fragments in your eye. Please let a study investigator know if any of these apply to you. Other potential risks include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that you will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points. Hospital for Special Surgery operates the MRI units within the safety guidelines established by General Electric Health Care, Milwaukee, Wisconsin."

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information [(i.e., names, social security numbers, medical record numbers)]; (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

Your condition may not get better from being in this study.

## 4. WHAT BENEFIT CAN YOU EXPECT?

This study includes experimental/investigational procedures which may not give you immediate benefit or any benefit. The knowledge gained may benefit others in the future.

## 5. COST

**Only the research procedures listed in Section 2 will be paid for by the study and will not be your financial responsibility.**

As indicated in Section 2, those costs which are considered Standard of Care for your treatment here at Hospital for Special Surgery will be your/or your insurance's responsibility. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any medical care costs not covered by your health insurance.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). For more information about the Financial Assistance Program or to request a Financial Assistance Application call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: http://www.hss.edu/patient-financial-assistance-notice.asp.

## 6. PREGNANCY

Due to inherent risks, HSS policy prevents pregnant women from receiving the type of intervention needed to qualify for this research study. Therefore, women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the 3 years of enrollment if you are participating in the Longitudinal Evaluation portion of the study. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately.

## 7. PAYMENT FOR PARTICIPATION

You will be paid $50 for your participation in this study following completion of the study.

You will receive payment for your participation in the form of a check, mailed to you. To receive this payment, your social security number will need to be collected. It will be securely stored and used solely as an identifier to ensure proper payment allocation.

## 8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

## 9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition.

You should ask the study doctor about other alternative treatments that may be available for your condition

## 10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, Memorial Sloan-Kettering Cancer Center, and the Medical College of Wisconsin. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor's behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, Memorial Sloan-Kettering Cancer Center, and the Medical College of Wisconsin. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products

resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is "blinded" so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

## 11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

## 12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

## 13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

## 14. SOURCE OF FUNDING

Funding for this study is provided by the National Institutes of Health (NIH).

## 15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Hollis Potter can be reached at 212-606-1023 during office hours and after business hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

## Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent to Participate in Research" form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

☐ I AM NOT in another research study at this time.

☐ I AM in another research study at this time.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

| | | |
|---|---|---|
| _____ | _____ | |
| Print Name of Participant | Signature of Participant | Date |
| _____ | _____ | |
| Print Name of Parent/Legal Guardian (if applicable)[1] | Signature of Parent/Legal Guardian | Date |
| _____ | _____ | |
| Print Name of Person Obtaining Consent | Signature of Person Obtaining Consent | Date |

_____

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

**NOTE TO INVESTIGATORS:**

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

[1] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

**HOSPITAL FOR SPECIAL SURGERY**
535 East 70th Street
New York, NY 10021

# INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Magnetic Resonance Imaging as a Biomarker For Adverse Local Tissue Reaction In Individuals With Hip Arthroplasty (Longitudinal arm)

PROTOCOL NO.:

SPONSOR: National Institutes of Health (NIH)

INVESTIGATOR: Hollis Potter MD

SITE(S): Hospital for Special Surgery / Division of MRI, Adult Reconstruction & Joint Replacement Division, Department of Pathology, Epidemiology & Biostatistics Core Facility

STUDY-RELATED PHONE NUMBER(S): 212-606-1886

IRB #: 13084

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you currently have a total hip replacement

**You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care**.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

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.

## 1. WHY IS THIS STUDY BEING DONE?

The purpose of the study is to create a method to detect and predict factors that could lead to success or failure of total hip replacement surgery. Your overall participation will involve a total **4** visits over a **4** year time period.

## 2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, one of the following routine and/or experimental procedures (Longitudinal Analysis) will be performed:

For this study, we will: 1) Ask you to have a physical examination with your surgeon; 2) Collect a blood sample (~1 teaspoon); 3) Ask you to fill out a questionnaire (~10 mins); 4) Acquire X-Ray images (~½ hr); 5) Acquire MRI images (~1 hr) to include a research sequence for seeing tissues near your total hip replacement.

| Study Visit # | Physical Exam | Blood Draw | Surveys / Questionnaires | X-Rays | MRIs |
|---|---|---|---|---|---|
| #1 | SOC (optional) | X | X | X | X |
| #2 | SOC (optional) | X | X | X | X |
| #3 | SOC (optional) | X | X | X | X |
| #4 | SOC (optional) | X | X | X | X |

**Those procedures marked with an "X" will be covered by the study.**
**Procedures that are marked "SOC" will be billed to you and/or your insurance**

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

Patients enrolled in the study may choose to have an office visit with their surgeon at the time of each study visit. Having an office visit is not required to participate in the study, and the **study will not pay for the cost associated with the office visit.**

A total of 210 subjects will participate in this portion of the study at HSS.

You qualify for this Longitudinal Analysis study if you:

1. Have a total hip replacement with a ceramic component.
2. Have a metal-on-polyethylene total hip replacement.
3. Have your original or revised total hip replacement.

You do not qualify if you:

1. Have occupational exposure to cobalt or chromium.
2. Have cemented components.
3. Presence of a metal-on-metal or recalled implant.
4. Standard contra-indications to MRI.

Your participation will involve a total of **4 study visits**, each of which are expected to last 2 hours. If, prior to enrollment in the current study, an X-ray or MRI was performed as a standard of care procedure in last 6 months during the follow up visit with the surgeon, it will be used as a part of the study. The subsequent visit will be scheduled by the research assistant.

**3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?**

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are:

The risks of blood drawing include mild pain, bruising, and very rarely infection at the place of the needle insertion.

X-rays: There are minimal risks to the patient from ionizing radiation resulting from the X-ray evaluation. During the conventional x-ray examination of your hip and pelvis, the "effective"* radiation dose is approximately equivalent to 32 months of the natural environmental background radiation that a person receives in the New York City annually. The risk from the radiation dose received from this procedure is too small to be detected. If the patient is especially concerned about radiation exposure, he or she may discuss this thoroughly with one of the investigators. The minimal dose of radiation and appropriate lead shielding is used. *The "effective"* dose is a calculation which estimates what dose, if given to the entire body, might produce approximately the same amount of risk as would the real dose actually received by the irradiated section.

Magnetic Resonance Imaging: The potential risks of MRI are minimal. There is no ionizing radiation involved with MR imaging. All imaging protocols and imaging coils used in this study are FDA approved, are validated for safety and are in current clinical use at the Hospital for Special Surgery. MRI is generally a well-tolerated procedure and you will be fully screened for MR safety before any imaging is started. In particular, you will be asked if you have any of the following: aneurysm clips on a cerebral artery, a deep brain stimulator, cardiac pace maker, wires or defibrillator, inner ear or cochlear implants, hearing aid, infusion pump or metal fragments in your eye. Please let a study investigator know if any of these apply to you. Other potential risks include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that you will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points. Hospital for Special Surgery operates the MRI units within the safety guidelines established by General Electric Health Care, Milwaukee, Wisconsin."

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numbers)]; (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

Your condition may not get better from being in this study.

## 4. WHAT BENEFIT CAN YOU EXPECT?

This study will provide you with the benefit of annual X-Rays (SOC optional), MRIs and blood tests to evaluate your health status as related to your total hip replacement. All data collected will be reviewed by the physicians providing your care at HSS. If the data indicate a specific course of treatment would be effective for maintaining the health of your total hip replacement, your orthopaedic surgeon will be in contact with you.The knowledge gained from this study may benefit others in the future.

## 5. COST

**Only the research procedures listed in Section 2 will be paid for by the study and will not be your financial responsibility**.

As indicated in Section 2, those costs which are considered Standard of Care for your treatment here at Hospital for Special Surgery will be your/or your insurance's responsibility. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any medical care costs not covered by your health insurance.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). For more information about the Financial Assistance Program or to request a Financial Assistance Application call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: http://www.hss.edu/patient-financial-assistance-notice.asp.

## 6. PREGNANCY

Due to inherent risks, HSS policy prevents pregnant women from receiving the type of intervention needed to qualify for this research study. Therefore, women who are pregnant or

nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the 3 years of enrollment if you are participating in the Longitudinal Evaluation portion of the study. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately.

## 7. PAYMENT FOR PARTICIPATION

You will be paid **$**50 for your participation in this study, following completion of each study visit.

You will receive payment for your participation in the form of a check, mailed to you. To receive this payment, your social security number will need to be collected. It will be securely stored and used solely as an identifier to ensure proper payment allocation.

## 8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

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## 9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition.

You should ask the study doctor about other alternative treatments that may be available for your condition

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- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, Memorial Sloan-Kettering Cancer Center, and the Medical College of Wisconsin. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor's behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, Memorial Sloan-Kettering Cancer Center, and the Medical College of Wisconsin. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is "blinded" so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

## 11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

## 12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

## 13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining

appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

## 14. SOURCE OF FUNDING

Funding for this study is provided by the National Institutes of Health (NIH).

## 15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Hollis Potter can be reached at 212-606-1023 during office hours and after business hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

## Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent to Participate in Research" form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

☐ I AM NOT in another research study at this time.

☐ I AM in another research study at this time.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

| | | |
|---|---|---|
| _____ | _____ | |
| Print Name of Participant | Signature of Participant | Date |
| _____ | _____ | |
| Print Name of Parent/Legal Guardian (if applicable)[1] | Signature of Parent/Legal Guardian | Date |
| _____ | _____ | |
| Print Name of Person Obtaining Consent | Signature of Person Obtaining Consent | Date |

_____

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

**NOTE TO INVESTIGATORS:**

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

[1] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.