### INFORMED CONSENT TO PARTICIPATE IN RESEARCH (Interventional and/or genetic study)

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Title:** |  | | |
| **Protocol No:** |  | **Sponsor:** | **<See Drafting Note>** |
| **Principal Investigator:** |  | **Phone Number:** |  |
| **Research Coordinator:** |  | **Coordinator Contact:** |  |
| **IRB #** |  | **Funding Support from:** |  |

<**Drafting Note**: PLEASE NOTE only list the outside company as “sponsor” if that company wrote the protocol. The entity giving HSS monetary or other support for a study may **NOT** be the “**Sponsor**”. For example, if an HSS researcher wrote the protocol, the “sponsor” should be listed as HSS even if funding is coming from an outside company. In that case, the outside company funding the HSS study would be listed next to “**Funding Support From**”. In other words, just because an external party provides HSS with funds, device, drug or services to accomplish an HSS written protocol, that outside entity should not be listed as the sponsor, but rather is a supporter of the HSS study>.

<**Drafting Note:** Please fill out the below chart for each study regarding the satellite sites of HSS>

|  |  |  |  |
| --- | --- | --- | --- |
| Participating Site(s) | Location | Participating Investigator | Site Phone Number |
| HSS Main Campus | East Side, NY | <List Principal Investigator> | <List site contact # or NA> |
| HSS Long Island | Uniondale, NY | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Queens | Fresh Meadows, NY | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Paramus | Paramus, NJ | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Stamford | Stamford, CT | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Westchester | White Plains, NY | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Florida – West Palm | West Palm Beach, FL | <LIST CO-Investigator or NA> | <List site contact # or NA> |
| HSS Florida - Wellington | Wellington, FL | <LIST CO-Investigator or NA> | <List site contact # or NA> |

**Hospital for Special Surgery  
535 East 70th Street**

**New York, NY 10021**

When we use the term “HSS” in this consent, that refers to Hospital for Special Surgery and its affiliates, including HSS-Florida Physicians LLC.

<**DRAFTING NOTE**: THIS INFORMED CONSENT FORM MUST BE WRITTEN AT THE 8TH GRADE READING LEVEL. WE ENCOURAGE YOU TO CONSULT THE LAY TERMS GLOSSARY AVAILABLE AT https://www.plainlanguage.gov/>

1. **OVERVIEW OF KEY INFORMATION REGARDING THIS RESEARCH STUDY**.

<**DRAFTING NOTE**: THIS SECTION, “OVERVIEW OF KEY INFORMATION”, IS MEANT TO BE A CONCISE AND FOCUSED SUMMARY OF THE KEY INFORMATION MOST LIKELY TO ASSIST A PROSPECTIVE SUBJECT (OR LEGALLY AUTHORIZED REPRESENTATIVE) IN UNDERSTANDING REASONS WHY ONE MIGHT OR MIGHT NOT WANT TO PARTICIPATE IN THE RESEARCH STUDY.>

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 <BRIEFLY EXPLAIN WHY THEY ARE BEING SELECTED, I.E., “YOU HAVE BEEN DIAGNOSED TO HAVE A CERTAIN CONDITION AND/OR ARE ABOUT TO UNDERGO A SPECIFIC INTERVENTION OR TREATMENT” OR “IN THE PAST YOU WERE DIAGNOSED AS HAVING A CERTAIN CONDITION AND/OR UNDERWENT A SPECIFIC INTERVENTION OR TREATMENT” OR “YOU ARE A HEALTHY SUBJECT” >. The information in this form is meant to help you decide whether or not to participate in this research study.

* Your **participation is voluntary.**
* You may decide not to participate in this research study.
* If you do participate, you may withdraw from the research study at any time.
* You do not have to participate in this study to receive treatment for your condition.

This document provides you with information about this study, including:

* Information about the procedures and the research, including risks, benefits, and alternatives, so you can make an informed decision about participating.
* Description of how your information will be used and shared.

Ask your study doctor or study staff to explain any words or information in this document that you do not understand. <**DRAFTING NOTE**: IF APPROPRIATE (E.G. CONSENT **NOT** BEING COLLECTED IN PRE-OP HOLDING ROOM), PLEASE ADD THE FOLLOWING> [You may take home a copy of this document to consider or discuss with family and friends before making your decision. You will need to sign this document to participate in this research.]

Funding for this study will be provided by [<SPONSOR> or for investigator-initiated research <FUNDING COMPANY NAME> or if applicable, and/or <DEPARTMENTAL FUNDS>]. [Throughout this document, <SPONSOR> is referred to as “Sponsor.”]

1. ***DOES THIS STUDY INVOLVE GENETIC TESTING OF YOUR BIOLOGICAL SAMPLES?***

\_\_\_ No, there is no genetic testing of your biological samples involved with this Study.

\_\_\_ Yes, the Study involves genetic testing of your biological samples. < **DRAFTING NOTE**: Add the following if genetic testing is part of the study> (If yes, please see Section 4 below for more information regarding genetic testing of your samples.)

1. ***WHY IS THIS STUDY BEING DONE*?**

The purpose of this study is to better understand <INSERT A CONCISE DESCRIPTION OF THE PRIMARY GOAL OF THE STUDY (*E.G.*, “HOW PEOPLE MAY BENEFIT FROM OR REACT DIFFERENTLY TO THE STUDY PROCEDURE” OR “TO DETERMINE WHETHER [xxx] (THE ‘STUDY DRUG’) IS SAFE AND EFFECTIVE FOR PEOPLE WITH YOUR MEDICAL CONDITION”)>. A total of <XX> subjects will participate in this study at HSS. <**DRAFTING NOTE:** INCLUDE THE REST OF THIS PARAGRAPH FOR INDUSTRY-SPONSORED STUDIES> [HSS is conducting this research at the request of <SPONSOR>. <SPONSOR> will reimburse HSS for conducting the study.]

HSS [if applicable, and <SPONSOR>] may use the results of the study to gain scientific knowledge, as described in Section 1(E) of this document (BENEFITS OF PARTICIPATING IN THE RESEARCH STUDY).

<**DRAFTING NOTE**: FOR PHASE I STUDIES, THE PURPOSE MUST INCLUDE EVALUATION OF “SAFETY”. FOR PHASE II AND PHASE III STUDIES, THE PURPOSE MUST INCLUDE EVALUATION OF “SAFETY AND EFFECTIVENESS”. FOR ALL STUDIES, “EXPERIMENTAL” USES OF DRUGS OR PROCEDURES MUST BE IDENTIFIED AS SUCH.>

1. ***YOUR INVOLVEMENT:***

* (X) number of visits are required by you over the next (X) months.
* Visits may occur at HSS main campus or satellite site(s) listed on page 1.
* Each of these visits may take up to (X) hour(s).
* Procedures will include <SUMMARY OF RESEARCH PROCEDURES>,
* Please see the chart listed in Section 2 below for additional information.

Your responsibilities as a participant in this study include:

* Signing this informed consent form;
* Following all study rules;
* Telling the study doctor truthfully about your complete medical history and other medications and supplements you are taking;
* Reporting any new problems, illnesses, or changes in medication during the study;
* Following the instructions of the study doctor and staff, including attending all your scheduled visits [and taking the study drug/ using the study device only as directed];
* Telling other doctors, nurses, and health care providers who provide treatment to you about your participation in this study; and
* Refraining from participating in any other studies while you are participating in this study unless your first notify your study doctor and discuss with your study doctor any potential risks posed by participation in more than one study.
* Your participation in this study may be terminated early by HSS [and/or <SPONSOR>]. This may happen for reasons such as: it is determined that you no longer meet the eligibility criteria to participate, you fail to follow the instructions given to you, or if HSS [<<if applicable>> and <SPONSOR>] decide[s] to end the study early.

1. ***MOST COMMON POSSIBLE RISKS AND DISCOMFORTS ASSOCIATED WITH YOUR PARTICIPATION IN THE RESEARCH STUDY:***

All research has some risk, which may include some side effects that make you feel unwell or uncomfortable or that could harm you. Ask the study doctor or staff if you have any questions about the risks or discomforts that may occur during this study.

During the study, you may have risks, discomforts and side effects from the study procedures. Most of these are listed in this informed consent form. Risks, discomforts and side effects may vary from person to person. Everyone taking part in the study will be watched carefully; however, doctors do not know all the risks, discomforts and side effects that may happen. These may be mild or serious, and in some cases may be very serious, long-lasting, or may never go away. <INCLUDE WHEN APPLICABLE> Your condition may or may not get worse from being in this study. [There is also a risk of death.] 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.

Let your study doctor know immediately if you experience any side effects or other health issues. Ask your study doctor to explain any side effects that you do not understand. [If your study doctor determines that there are safety concerns, then you may be asked to return to HSS or your doctor’s office to complete additional study procedures, such as a brief physical examination and an assessment of any side effects that you may have experienced.] If your side effects are severe, your study doctor may advise you to withdraw from the study.

Possible risks, discomforts and side effects that you may experience include:

<**DRAFTING NOTE**: LIST THE MOST COMMON POSSIBLE RISKS AND DISCOMFORTS IN A BULLET POINT FORMAT. INCLUDE DISCOMFORTS FROM STUDY PROCEDURES, SUCH AS BLOOD DRAWS>< **DRAFTING NOTE**: STANDARD RISK LANGUAGE HAS BEEN DEVELOPED FOR USE IN OUR INFORMED CONSENT FORMS TO ENSURE THAT OUR INFORMED CONSENT FORMS CONSISTENTLY AND ACCURATELY DESCRIBE THE RISKS ASSOCIATED WITH CERTAIN COMMON PROCEDURES – SPECIFICALLY, X-RAYS, CT SCANS, NUCLEAR MEDICINE, MRI AND ULTRASOUND. YOU MAY FIND THIS LANGUAGE ON THE INSTITUTIONAL REVIEW BOARD SITE ON THE INTRANET AT <http://intranet.hss.edu/research/IRB/files/Language_for_Risks_of_Imaging_Studies.doc>>

< **DRAFTING NOTE**: ADDRESS THE RISK TO PATIENT PRIVACY, AS APPROPRIATE BASED ON THE SPECIFIC INFORMATION BEING KEPT IN THE STUDY – FOR EXAMPLE, >

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)]<MODIFY AS NECESSARY>; (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.

< **DRAFTING NOTE**: INCLUDE THE FOLLOWING PARAGRAPH ONLY IF GENETIC TESTING WILL BE PERFORMED.>

There may be some risks associated with genetic testing that may be performed on your biosample. Those risks are described in Section of the document entitled “GENETIC TESTING”.

1. ***BENEFITS OF PARTICIPATING IN THE RESEARCH STUDY:***

< **DRAFTING NOTE**: IF THE STUDY PRESENTS ANY POTENTIAL **DIRECT BENEFITS** FOR THE PARTICIPANT, PLEASE INCLUDE A DESCRIPTION OF POTENTIAL DIRECT BENEFITS.>

<**DRAFTING NOTE**: PLEASE SELECT THE PARAGRAPH BELOW THAT BEST FITS YOUR STUDY. IF NEITHER APPLIES, PLEASE EDIT AS NECESSARY TO APPLY TO YOUR STUDY OR DELETE BOTH STATEMENTS AND WRITE A DESCRIPTION OF POTENTIAL STUDY BENEFITS:

This study includes experimental/investigational procedures. While it is possible that these procedures will benefit you, their benefits are not yet fully known. So, it is possible that you will not benefit from the procedures.

<OR>

This study is comparing two standard of care procedures to determine which may be more effective. While you may benefit from receiving one of the study procedures, it is not currently known to what extent you may benefit from one procedure over the other. The knowledge gained from this study may benefit others in the future.

The knowledge gained from this study may benefit others in the future. Specifically, this study may help scientists to <INSERT MORE CONCISE DESCIPRTION OF ALL STUDY GOALS, INCLUDING DOWNSTREAM AND INDIRECT GOALS, BREAKING OUT INTO BULLET POINTS WHERE NECESSARY (*E.G.,* “(1) UNDERSTAND WHY SOME PEOPLE RESPOND BETTER TO PROCEDURE X THAN PROCEDURE Y, (2) UNDERSTAND WHAT SIDE EFFECTS PROCEDURE Y MIGHTS HAVE; AND (3) IMPROVE FUTURE CLINICAL RESEARCH STUDIES.”)>

1. ***ALTERNATIVES TO BEING IN THE STUDY***

ALTERNATIVES: IS TREATMENT STILL 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. If you decide not to participate in this study, you may receive the standard treatment for your condition. There may be other studies available that you could participate in.

< **DRAFTING NOTE**: ANY STUDY MEDICATIONS/DEVICES OR TREATMENTS THAT ARE REASONABLY AVAILABLE OUTSIDE THE STUDY (i.e., “OFF PROTOCOL”) MUST ALSO BE DISCLOSED>

The following medications and/or procedures are available as common alternative treatments for your condition:

< **DRAFTING NOTE**: LIST THE MOST COMMON ALTERNATIVE TREATMENTS, IF ANY, HERE>

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

***G. WHAT HAPPENS IF YOU CHANGE YOUR MIND?***

Your participation in this study is voluntary. You may decide not to participate at any time by informing your study doctor in writing that you no longer wish to participate in the study. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide to leave the study before the last study visit, it is important that you tell the study doctor so that the study doctor can evaluate risks to you and discuss any follow-up care that could be helpful to you. It is helpful if you could explain your reasons for leaving the study.

If you decide to leave the study, no new information or samples will be collected from you after you withdraw. Information collected about you before you withdraw may be used by HSS or <SPONSOR> in connection with the study for certain reasons, such as to check the accuracy of the study, maintain the integrity of the study data, or account for you leaving the study.

<INCLUDE IF BIOLOGICAL SAMPLES ARE COLLECTED> If you withdraw your consent to use the samples before they are sent to the laboratory for processing and analysis and you wish to have the samples destroyed, reasonable efforts will be made to ensure your samples are destroyed. If your samples have already been processed and analyzed, the results cannot be destroyed and will continue to be available to <SPONSOR> and HSS.

1. **WHAT WILL YOUR PARTICIPATION REQUIRE?**

If you decide to be in this study, the following procedures will be performed:

< **DRAFTING NOTE**: PLEASE SEE THE BELOW SAMPLE CHART. PLEASE MODIFY THE CHART ACCORDING TO THE REQUIREMENTS OF YOUR STUDY. MARK WITH AN “RES” TO INDICATE RESEARCH PROCEDURES TO BE PERFORMED AND MARK “SOC” TO INDICATE STANDARD OF CARE PROCEDURES OR LIST STUDY PROCEDURES FOR EACH STUDY VISIT USING A BULLET FORMAT. ANY PROCEDURES THAT ARE STANDARD OF CARE SHOULD BE IDENTIFIED AS SUCH.>

< **DRAFTING NOTE:** **IMPORTANT**, please work with HSS Clinical Research Finance to ensure that the below study calendar matches the budget and EPIC billing grid with respect to SOC vs RES>

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| RES= Research procedures  SOC= Standard of care (care you would receive if you were not participating in this study) | | | | | | | | |
| Study Visit # | Blood Draw | Surveys / Questionnaires | Randomization | Surgery | X-Rays | MRIs | Physical Exam | Phone Contacts |
| #1 (i.e. Wk 1 postoperatively |  | RES |  |  | SOC | RES | SOC |  |
| #2 |  |  |  |  |  |  |  |  |
| #3 |  |  |  |  |  |  |  |  |
| #4 |  |  |  |  |  |  |  |  |

<DRAFTING NOTE: PLEASE ADD BELOW A BRIEF DESCRIPTION OF THE RESEARCH PROCEDURES TO BE CONDUCTED>

<DRAFTING NOTE: If a research procedure must occur at a specific site, please specify for the subject e.g. surgery can only occur on the main campus.>

< DRAFTING NOTE: INCLUDE IF APPLICABLE> This study will select your treatment by chance. You will be assigned at random to one of <INSERT # OF POSSIBLE STUDY GROUPS> study groups that will receive different treatments, or no treatment. The randomization process is comparable to (or similar to) the flip of a coin. It is not known if any treatment you receive will benefit you. It is hoped the knowledge gained will benefit others in the future. <DRAFTING NOTE: IF THE STUDY SUBJECT WILL BE BLINDED TO THE TEST ARTICLE/DRUG, INSERT THE FOLLOWING LANGUAGE TO EXPLAIN BLINDING, EDITING AS NECESSARY> [During the study you will be “blinded” to whether you are receiving the Study Drug/Study Device which means you will not know if you are receiving the Study Drug/Study Device or the placebo. In the event of an emergency, the “blind” can be broken. If the research is “double blind” this means that during the course of the study, neither you nor the research team will know if you are receiving the Study Drug/Study Device or the placebo.]

< DRAFTING NOTE: INCLUDE IF APPLICABLE IF THIS STUDY WILL USE MyCap> As part of your enrollment in this study, you will be asked to download a free application to your mobile phone or tablet entitled MyCap. A member of the study team will provide you with a unique QR code (barcode), which you will scan with your smartphone or tablet camera to gain access to the MyCap application. Please note that the use of MyCap application may affect your mobile monthly data usage. You should review the terms and conditions and privacy policy of MyCap before downloading the MyCap application to learn how MyCap uses the information it collects from you.

1. **COST TO YOU**

< **DRAFTING NOTE**: PLEASE CHOOSE THE ALTERNATIVE THAT APPLIES TO YOUR STUDY, REMOVING THE ALTERNATIVE THAT DOES NOT APPLY >

**<Alternative 1: ONLY RESEARCH COSTS COVERED; SUBJECT STILL RESPONSIBLE FOR MEDICAL COSTS>**

The items and services that you receive because you are participating in the study will be provided to you at no charge. These research procedures are marked as “RES” in Section 2 of this document.

You or your insurance company are financially responsible for the costs of routine medical care provided to you over the course of the study that you would have received as part of the treatment of your condition even if you were not participating in the study. These procedures are marked as “SOC” in Section 2 of this document. 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, and any costs for procedures marked “SOC**”** that are not covered by your health insurance. Financial assistance may be available in certain cases. To learn about whether financial assistance may be available in your case, please call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: https://www.hss.edu/financial-assistance.asp.

<**Alternative 2: NO COST TO SUBJECT WHERE ALL COSTS (INCLUDING SOC COSTS) ARE PAID FOR BY RESEARCH FUNDS OR SPONSOR>**

There will be no cost to you for participation in this study. <INSERT BRIEF DESCRIPTION OF WHY – E.G., “…because the sponsor is paying for the cost of all medical care you are receiving as part of this study.” <OR> “…because this study does not involve any additional visits, tests, or procedures.”>

(**PHOTOGRAPHY:** <**DRAFTING NOTE:** IF**PHOTOGRAPHING OF STUDY SUBJECTS** will occur as part of the study. Add the below section. If not, please renumber the consent sections.>)

1. **PHOTOGRAPHY**

<**DRAFTING NOTE: If the study includes photography please include the following language to protect participants identity.>** As part of this study images will be captured of you. Those images will capture the following: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_<**DRAFTING NOTE: State what part(s) of the study subject will be captured in the images and if will be photographs or video>**

These images will be shared with: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ as part of the study. <**DRAFTING NOTE:** State who will have access to the images as part of the study>

HSS will only show the images of you from the mentioned areas without identifying your facial characteristics, tattoos, scars, moles, body piercing and /or birthmarks. By signing this consent, you give HSS permission to use these images in publications and conferences as long as your facial characteristics, tattoos, scars, moles, body piercing and /or birthmarks are scrambled and obscured to protect your identity.

(**GENETICS SECTION:** <**DRAFTING NOTE:** IF **GENETIC TESTING** WILL OCCUR AS PART OF THE STUDY. Add the below section. If not, please delete and renumber the consent sections.>)

1. **GENETIC TESTING**

What is a Gene?

DNA is the material that allows for the inheritance of many human traits, such as hair and eye color or the risk of some diseases. DNA is contained in the cells that make up the body and carries the instructions for your body’s development and functions.

A piece of DNA that determines a specific function of a cell is called a “gene.” Everyone’s DNA is different, and differences in DNA are called “variants.” Some variants do not cause any medical problems, but other variants in a gene can lead to disease. Sometimes, we do not have enough information to know whether a specific variant causes disease or not. The goal of genetic research is to identify genetic variants that cause disease.

Genetic testing as part of research is not for clinical care or treatments

Collection and Use of DNA: Researchers collect and analyze your DNA and/or RNA (RNA is a molecule made from your DNA) to answer a research question. It is important for you to understand that this analysis is being performed in order to conduct research, and not to provide you with medical care. Reports about research done with your sample will not be given to you or your doctor and will not have an effect on your medical care. It is likely that we will not be able to provide you with any information regarding whether you currently have or are predisposed to developing disease <**DRAFTING NOTE**: INSERT THE NAME OF DISEASE FOR WHICH THE TESTING IS OCCURRING >.

Participation in this research study does not replace a clinical genetics evaluation or clinical care. Whether or not you decide to participate in this study, you may want to discuss pursuing clinical genetic testing with your treating physician You may ALSO wish to obtain professional genetic counseling prior to signing this informed consent. Please note, however, genetic counseling is not offered as part of your participation in the research study.

General Description of The Genetic Test That Will Be Done On Your Biosample As Part Of This Study: <**DRAFTING NOTE**: INSERT A GENERAL DESCRIPTION OF THE GENETIC TEST THAT WILL BE CARRIED OUT ON THE BIOSPECIMEN. IF WHOLE GENOME SEQUENCING WILL BE PERFORMED, STATE THAT EXPLICITLY IN THE FORM. >

< **DRAFTING NOTE**: STATE THE PURPOSE OF THE GENETIC TEST. INCLUDE ANY FUTURE OR DOWNSTREAM USES OF GENETIC INFORMATION **>**

The specific disease or condition for which the genetic tests will be testing for is/are:<**DRAFTING NOTE**: please insert the specific diseases or conditions being tested for.> {NOTE: if the research protocol does not permit such degree of specificity, please state so in your submission to the IRB so that the IRB may consider waivers of or modifications to this provision. }

Statement Regarding Retention, Maintenance, and Disclosure of Genetic Test Results: The genetic testing performed in connection with this study is performed for research purposes and generally has no clear meaning for your health or the health of your family members. **<< DRAFTING NOTE**: ADD THIS SENTENCE FOR NON-FLORIDA STUDIES: We have no plans to return genetic test results to you or your doctor.>> However, we may return results to you or your doctor if we believe the results have important meaning for your health <<**RESEARCH IN FLORIDA DRAFTING NOTE**: ADD THIS STATEMENT FOR FLORIDA STUDY SUBJECTS: Moreover, upon your written request, the results of your genetic test will be made available to your physician.>>

With Whom Will the Results of the Genetic Test Be Shared: The results of the genetic tests will be shared with researchers involved with the study, as well as <**DRAFTING NOTE:** Please fill in the categories of individuals or organizations with whom the genetic test results will be shared >. Please note that the results of the genetic tests on your samples will not be shared directly with you, but may be shared with your doctor if we believe the results have important meaning for your health and will be made available to your physician. << **RESEARCH IN FLORIDA DRAFTING NOTE**: ADD THIS STATEMENT FOR FLORIDA STUDY SUBJECTS: upon your written request. Moreover, as stated above, upon your written request, the results of your genetic test will be made available to your physician.>>

<**DRAFTING NOTE:** Please include this language unless the investigator is certain that genomic data will never be shared in this manner. When the research is NIH-funded and subject to NIH’s genomic data sharing policy, this language **must** be included in order to satisfy the requirements of such policy, which mandate making large-scale genomic data available in an NIH-designated repository.>

{To comply with NIH policy ((where applicable) and requirements of different scientific journals, and because there are recognized benefits that sharing of data can accelerate research, datasets generated with samples from this biorepository may be put into other third-party databases along with information from other studies and stored for an indefinite period of time. We might share genomic data generated from your samples with third-party databases that are open to the public (*e.g.*, access to data will **not** require review or approval by an NIH Data Access Committee). You should be aware that datasets in these third-party databases may be used for any purposes and the data are often used for research not related to the specific aims of the study for which they were originally collected. Therefore, your genomic data might be used for future research that is not related to the aims of this study. Prior to submitting your data to another database, your data will be stripped of personally identifiable information (e.g., your name, date of birth and medical record number) and coded in such a way as to protect your identity. However, as with all genomic data, even without personally identifiable information, it may be possible to re-identify genomic data you're your confidentiality cannot be guaranteed. The risk of re-identification can change over time due to computational methods, analytic technologies, or new techniques that allow for re-identification of data. Re-identified data could potentially be used to discriminate against or stigmatize you, your family, or groups to which you belong.}

Use and Retention of Your Samples: No tests other than the ones that you authorize in this form or in subsequent authorization forms will be performed on your identifiable samples and your identifiable samples will be destroyed at the end of the study unless you authorize retention of the samples as part of a research repository.

**Risk Involved With Genetic Testing: Genetic testing may generate information about you or your family that could relate to your genetic predisposition to specific diseases or medical conditions. Genetic testing may also confirm that you currently have a particular medical condition. Although reasonable efforts will be made to ensure that any information about you will not be wrongly disclosed or used, there is always the possibility that it may be inadvertently disclosed, which could cause emotional distress to you or your family.**

**A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:**

* **Health insurance companies and group health plans may not request your genetic information that we get from this research.**
* **Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.**
* **Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.**

**All health insurance companies and group health plans and all employers with 15 or more people must follow this law. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Additionally, any collection, storage and transfer of data related to your biological material in the context of medical research projects entails the risk of breaches of confidentiality (*e.g*. the possibility of identifying you). These risks are low but cannot be completely excluded and rise with increasing amounts of linked data, particularly when you make information available on the internet. As described below, however, in the section entitled “Confidentiality and Privacy,” we will take precautions to protect your medical information from being wrongly used or disclosed.**

**PREGNANCY < DRAFTING NOTE**: INCLUDE AS APPLICABLE (E.G., NOT APPLICABLE TO STUDIES INVOLVING QUESTIONNAIRES ONLY)> << **RESEARCH IN FLORIDA DRAFTING NOTE**: INCLUDEFOR FLORIDA STUDY SUBJECTS ONLY: **pregnant minors (i.e, under age 18) in Florida** **cannot consent to research** and **should NOT be asked to sign a research consent**.>>

< **DRAFTING NOTE**: If this informed consent form is being prepared for a study that has specific requirements about women of child-bearing age OR MEN WITH FEMALE PARTNERS, the INVESTIGATOR should provide the specific wording for this section, which should include pregnancy testing and the types of contraception to be used.>

< AS APPLICABLE>

Due to the risks associated with (<**DRAFTING NOTE:** INCLUDE THE SPECIFIC PROCEDURE(S) OR INTERVENTION THAT IS SPECIFICALLY CONTRAINDICATED FOR WOMEN WHO ARE PREGNANT>), pregnant women may not receive the type of intervention needed to participate in this research study [and men may not impregnate a woman while participating in the study]. Therefore, women who are pregnant or nursing a child are not permitted to participate in this study. For the safety of yourself and any unborn child, before participating in this study, women are required to confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during <DURATION>. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately. Additionally, if you are capable of getting pregnant and are sexually active with someone of the opposite gender, you must use a form of contraception that has been approved by your study doctor while participating in the study. In some cases, your study doctor may instruct you and/or your partner to use two forms of contraception, such as birth control (IUD, pill, etc.) and a condom.

<OR>

If you are currently pregnant or nursing a child, you may still participate in this study. Also, if you become pregnant during this study, you may continue to participate in this study. You should, however, inform your doctor immediately if you are pregnant and/or nursing a child to ensure that all necessary precautions are taken to protect yourself and/or your child.

(<**DRAFTING NOTE: PREGNANT PARTNERS**: If a sponsor is requesting a pregnant partner consent form and requests that a male study subject notify the study doctor if his partner becomes pregnant during the study, it is HSS’s policy that the consent form for the study (i.e., the consent form signed by the male subject) read only that such male subject communicate to his partner that she may volunteer to have the information about her pregnancy tracked by the sponsor. If she communicates to the male subject that she is willing to participate in such tracking, the male subject will let the study doctor know and the study doctor will facilitate providing a pregnant partner consent form pursuant to the sponsor’s instructions**.**) HSS can accept the following language>:

“If you are a male participant and your partner becomes pregnant, you agree to communicate to your partner that she may volunteer to have the information about her pregnancy tracked by the sponsor. If she communicates to the you that she is willing to participate in such tracking, you will let the study doctor know and the study doctor will facilitate a pregnant partner consent form for your partner.”

1. **PAYMENT FOR PARTICIPATION**

You will not be paid for your participation in this study.

**<OR>**

You will be paid $\*\*\* for your participation in this study. You will also receive reimbursement for travel expenses up to but not to exceed $\*\*\* with proof of receipt. You will not be reimbursed for any other expenses. You are required to provide a valid Social Security Number in order to receive payment for your participation or reimbursement for travel. Payment will be completed in the form of a check mailed to you at the address you listed in your medical records.

Depending on the amount of payments you receive from HSS over the year, tax law may require the HSS Finance Department to report that amount to the Internal Revenue Service (IRS) or other federal and state agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from HSS in a calendar year. You would be responsible for the payment of any tax that may be due.

1. **COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY**

Use of the findings of this study, information derived from your participation in the study and/or samples you have donated which are used in research may result in new products, tests, or discoveries, including establishing a cell line that could be patented and licensed. In some instances, these may have potential commercial value and may be developed and owned by the investigators, by Hospital for Special Surgery and/or by others. There are no plans to provide financial compensation to you should this occur. Therefore, you would not share in any financial benefits from these products, tests, or discoveries or cell lines.

1. **AUTHORIZATION FOR USE AND DISCLOSURE OF PRIVATE HEALTH INFORMATION FOR 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 your private health information for purposes of this study. *Private health information* means the health information in your medical or other healthcare records that can identify you.

Your Private Health Information Will Be Used and Disclosed to Accomplish the Study: We are asking you to authorize the use and disclosure (release of your private health information) for this research study. The private health information that will be used and/or disclosed to accomplish the study include:

<**Drafting Note:** FILL IN THE LIST OF PRIVATE INFORMATION. Please note that statements such as “Your entire medical record” or “Your labs” are **too broad**. Rather, “Your medical record for the past 5 years that relates to (the *specific disease or condition being studied*) or “Your labs for the past 5 years that relate to (the *specific disease or condition being studied*) (i.e., Narrowing the disclosure to the minimum necessary to accomplish this study as is required by HIPAA.) Also, if any of the following will be disclosed, they must be specifically named below: HIV related information, Substance Use Disorder or information regarding STDs>

* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<**Drafting Note:** If HSS will be transmitting any of the below highly identifiable information the subject must explicitly consent. If that is the case, you must include the below language. If none of the highly identifiable information is being transmitted out of HSS as part of the study, the below bracketed language can be removed from the consent. It must be determined whether the subject may refuse to agree to the disclosure of these data and still remain in the study. You will select the applicable option below>

**Authorization for The Disclosure and Use Private Health Information that More Directly Identifies you to Accomplish the Study (“Highly Identifiable Information”):**

**The following Highly Identifiable Information will be used and/or disclosed to accomplish the study:**

* **Your name (first and last);**
* **Your street address;**
* **Your email address;**
* **Your telephone number;**
* **Social Security number**

**In order to participate in the study [you must] [you do not need to] agree to the sharing of the above Highly Identifiable Information. [You understand that if you do not authorize HSS to disclose the Highly Identifiable Information you will NOT be able to participate in this study. Please indicate your consent to share such information:]**

**Authorize: \_\_\_\_\_\_ By initialing here, I give my consent and authorize HSS to disclose the Highly Identifiable Information listed above to [*enter name of recipient institution or entity*] to be used solely to accomplish this study. I do not give [*enter name of recipient institution or entity*] my consent to use such information for any other purpose.**

**[Do not Authorize:\_\_\_\_\_\_\_ By initialing here, I do not give my consent nor my authorization to HSS to share the Highly Identifiable Information listed above for this study. [Drafting Note: If the optional language “You must” agree to the sharing of the above identifiable information……is selected above, this section “Do not Authorize”, should be deleted as the individual will not be able to opt out. Also, to avoid confusion if the individual must share their information to be a study subject, but he/she checks the language to deny authorization to HSS to share that information, that could cause confusion.]**

HSS and the HSS Study Team Can Use and Disclose Your Private Health Information to accomplish the Study: By signing this consent, you permit HSS and HSS the study doctor and the study doctor’s research team at HSS to use your private health information for the study. You also permit HSS and HSS-Florida Physicians LLC to release your private health information to the people and organizations listed below to accomplish this study.

With Whom HSS May Share Your Private Health Information to accomplish the purposes of the Research Study:

<INCLUDE THE FOLLOWING AS APPLICABLE; IF IN DOUBT, INCLUDE ALL>

* 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, Weill Cornell Medical Center, Rockefeller University, Memorial Sloan-Kettering Cancer Center and HSS-Florida Physicians LLC <INCLUDE ADDITIONAL ENTITIES AS APPLICABLE>. This includes the research staff and medical staff at each institution.
* The Patient Advocate or Research Ombudsman at these institutions.
* Staff members of HSS main campus or HSS satellite site(s) responsible for administering clinical trials and other research activities, as well as other administrative or management activities of HSS.
* 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, are owned by the sponsor, or acquire rights to the product under study from 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, Weill Cornell Medical Center and, Memorial Sloan-Kettering Cancer Center. <INCLUDE ANY ADDITIONAL IRBs AS APPLICABLE>. 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.
* HSS contractors to assist in achieving the purposes of the study but only where such contractors agree to keep your information confidential.
* 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.

The Purpose for Which Your Private Health Information Will Be Used or Disclosed:

Your private health information will be released to the people and organizations listed above to carry out this study. Specifically, this information will be used to <**INCLUDE THE FOLLOWING AS APPLICABLE AND ADD AS APPLICABLE**> determine whether you meet the conditions for participation in this study; to compare your earlier test results to the findings from this study; to use your previous laboratory results in place of, or in addition to, some of the lab results needed for this study.

The sponsor of the study will use your private health information as part of its analysis and evaluation of the results of this study. People working for the sponsor also visit HSS and view your private health information to make sure this study is being done correctly.

Your private health information may be disclosed to the FDA and to governmental agencies in other countries so the sponsor can get approval to market new products or to continue marketing existing products. Your private health information may also be used to meet the reporting requirements of governmental agencies.

While the results of this study may be published in scientific journals or presented at medical meetings, your private health information will not be disclosed in any publications without your consent.

You Can Refuse to Authorize the Use and Disclosure of Your Private Health Information for the Research Study: You do not have to give HSS permission to use or disclose your private health information. Such permission is voluntary. However, if you do not give HSS this permission, you will not be able to join the research study. Your decision to not sign this permission will not affect your current and/or future treatment, health care services, or eligibility for benefits you receive from HSS or your HSS health care providers.

Expiration Date of This Authorization to Use and Disclose Your Private Health Information: This permission to use and disclose your private health information will never expire unless you revoke it.

Can You See the Private Health Information Collected as Part of the Study? 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).

You May Revoke This Authorization: You may change your mind and take back this Authorization at any time.  If you take it back and no new health information that might identify you will be gathered. However, the researchers may still use the private health information they have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization. To take back the Authorization, you must write to the Principal Investigator at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

Once Disclosed Your Private Health Information May No Longer Be Protected by the Privacy Laws: Some persons or organizations who receive your private health information may not be required by law to protect it in the same way as HSS, and they may share your information with others without your permission, if permitted to do so by laws governing them. Therefore, your private health information may be released to others without your permission.

1. **CONFIDENTIALITY and PRIVACY.**

Any and all private health information about you obtained through this study, including any results of genetic testing, is private and confidential, and will not be disclosed, unless permitted or required by law or by this consent form. If a disclosure of information is not authorized by law or by this consent form that disclosure will not be made without your further written informed consent.

Identifiers might be removed from your private health information or your identifiable samples and, after such removal, the information or biosamples could be used for future research studies by HSS or distributed to another investigator, institution or company for future research studies without HSS getting additional consent from you. As noted above, FDA and other regulatory agencies may have access to identifiable information about you in connection with the study, including through inspecting your records at HSS or remotely

[DESCRIBE HERE THE PROCEDURES THAT YOU WILL USE TO PROTECT THE STUDY (INCLUDING GENETIC) INFORMATION OF RESEARCH SUBJECTS, SUCH AS SECURITY PASSWORDS ON COMPUTERS IN WHICH INFORMATION IS MAINTAINED, ANY APPLICABLE DE-IDENTIFICATION OR CODING PROCEDURES, AND THE SAFEGUARDS THAT WILL BE APPLIED TO STORED SPECIMENS AND DATA].

[<PLEASE INSERT THE BELOW SECTION REGARDING CERTIFICATE OF CONFIDENTIALITY WHERE IT IS APPLICABLE TO YOUR STUDY>]

[Certificate of Confidentiality

This study has a Certificate of Confidentiality. A Certificate of Confidentiality protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biosamples containing identifiable, sensitive information without your authorization. The Certificate prohibits disclosure in response to demands in a court proceeding, such as a subpoena without your authorization. These certificates protect names or any information, documents, or biospecimens containing identifiable, sensitive information related to a research participant. Please contact the IRB at 212.606.1238 for more information about the Certificate of Confidentiality.

The Certificate DOES NOT stop reporting that may be required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a United States federal or state government agency that sponsors the study (if any) from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

<INCLUDE IF APPLICABLE> 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. In order to comply with journal submission requirements, the Web site may also include a plan describing how your de-identified data may be shared with other investigators. You understand that we may share your de-identified data with other researchers due to these requirements.

< OPTIONAL RESEARCH REPOSITORY SECTION: DRAFTING NOTE: INCLUDE IF APPLICABLE IF THIS STUDY WILL USE A RESEARCH REPOSITORY FOR FUTURE RESEARCH. IF NOT, PLEASE DELETE THE BELOW SECTION AND RENUMBER THE SECTIONS.>

1. **RESEARCH REPOSITORY**

By signing this consent form, you agree to give your samples **(LIST APPLICABLE SAMPLE TYPES, I.E., BLOOD, SALIVA, STOOLS, ETC.)** to the study team for research purposes described above.

You may also agree to participate in the optional research repository with any sample(s) (**LIST APPLICABLE SAMPLE TYPES)** that is leftover after the research described above. You can still participate in the main study even if you choose not to participate in this optional research repository.

**What is a Research Repository?** The research repository (database) is a collection of information from the health and medical records of many individuals and will include identifiable samples (like your tissue). The repository will be located at HSS or another facility designated by HSS. Information and specimens may be shared from the repository with researchers who study medical conditions and diseases.

The information in the repository (database) is coded so that only researchers at HSS who hold the key to the code may re-identify each person whose information is collected. HSS will not share any directly identifiable information with other researchers unless those researchers promise to keep the information confidential.

Biological samples [**define types of specimens to be collected**] that you contribute for this study will be maintained for as long as it is deemed useful for research purposes, after which time the sample will be destroyed. If your sample is used for any future studies, it will either be completely stripped of any information that could be used to identify you, or it will be coded in such a way as to protect your identity, under the supervision of the Hospital’s research review committee. [**NOTE THAT TISSUE REPOSITORIES FOR FUTURE GENETIC TESTING MUST MEET ONE OF THESE TWO CRITERIA: EITHER TOTALLY STRIPPED OF IDENTIFYING INFORMATION, OR CODED UNDER A CODING PROTOCOL APPROVED BY THE IRB BEFORE STORAGE**.]

**PERMISSION TO STORE AND USE YOUR HEALTH INFORMATION AND BIOSAMPLE FOR FUTURE RESEARCH:**

Permission to Store and Use Your Samples and Health Information for Future Research in <**State Specific Disease or Illness>**: The repository may keep my health information, including genetic information that might identify me and/or my samples **(LIST APPLICABLE SAMPLE TYPES)**, associated with information that may identify me with those samples, and may use them and share them with others outside HSS for future research in *the same topics as the research described above that*

***DOES NOT include genetic testing****; OR*

***MAY include genetic testing on my samples for the purpose of understanding and treating others with*** <**State Specific Disease or Illness>**

I understand that if my information goes to an entity outside HSS, privacy laws may not apply to the use of my samples or information by that other entity. Such other entities may include not-for profit and/or for-profit entities.

Permission to Store and Use Your Samples and Health Information for Future General Research; No Genetic Testing: The repository may keep my health information, including genetic information that might identify me and/or my samples **(LIST APPLICABLE SAMPLE TYPES),** associated with information that may identify me with those samples, and may use them and share them with others outside HSS for future research in the *same topics as the research described above* **AND** *for future general research into other topics that:*

***DOES NOT include genetic testing***; OR

***MAY include genetic testing on my samples for the purpose of understanding and treating human disease***

I understand that if my information goes to an entity outside HSS, privacy laws may not apply to the use of my samples or information by that other entity. Such other entities may include not-for profit and/or for-profit entities.

The repository may **NOT** keep health information that might identify me or my samples **(LIST APPLICABLE SAMPLE TYPES)** for a research repository.

Participation is Voluntary: I understand that my specimens will be destroyed when no longer useful for research. I further understand that I have the right to refuse the specimen donation to the research repository, and that this will in no way influence my ability to participate in the main study or my treatment or eligibility to participate in research studies or clinical trials at HSS.

Future Genetic Testing on Stored Samples: No genetic tests will be performed on any stored, identifiable samples unless you have given your consent to such testing above. In no event will any directly identifying information about you derived from genetic tests performed on your stored samples or information linking you with specific results of genetic tests released to any organization or person without your explicit written consent to release of that information for the purposes set forth in such a written consent document.

Withdrawing Consent to Store Your Sample and Destruction of your Sample: You have the right to withdraw your consent to the storage and/or future genetic testing of your biological sample at any time by contacting the Principal Investigator of this study, **<Drafting Note**: INSERT NAME OF PRINCIPAL INVESTIGATOR**>** at the following phone number **<Drafting Note**: INSERT NUMBER FOR SUBJECT TO CALL FOR THESE PURPOSES **>** If you do so, any portion of your sample that has not already been used for research purposes will be destroyed. If your sample had been stripped of all information that could identify you, however, it will not be possible to remove your sample from those samples that are stored for future research.

1. **CONTACTING YOU AFTER THE CONCLUSION OF THE STUDY:**

Do you give the HSS researchers permission to contact you in the future? Such contact could be, for example, to get more information from you that may be needed for this research, to explain the results of this study, or to notify you of medical information that could help you or your family member, discuss how your samples might be used, or to discuss possible participation in another research project?

Yes No

Do you give permission to have information derived from your samples given to other researchers at Hospital for special surgery or others outside of HSS for use in research which research may be either related or unrelated to the purpose of the study?

Yes No

Do you give the researchers your permission to ask your next of kin or the representative of your estate for consent to do further testing on your biosample after my death and disclose the results to my family.

Yes No

Please note that, except for the above with your permission, in no event will we contact your family members for clinical, research or other purposes without your consent with respect to the specific family members who will be contacted and the specific purpose of the contact.

Risks and Benefits of Allowing Future Contact: The risks of allowing us to contact you are that we may have information that cause some emotional distress, but the benefits are that we may have information that could help you in your medical planning and decision-making. Benefits for society may include providing further information about the genetic basis of [disease X] as well as the development of safe and effective therapies for that illness.

1. **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.

< **DRAFTING NOTE**: If there is a potential conflict of interest, the paragraphs below should be FILLED IN AND incorporated in the INFORMED consent form, WITH ANY NECESSARY MODIFICATIONS TO ACCURATELY AND APPROPRIATELY DESCRIBE THE POTENTIAL CONFLICT OF INTEREST. Otherwise, they should be deleted from the INFORMED consent form.>

In this study, Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_, the Principal Investigator, [and Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_, Co-Investigator], have each reported to HSS that they each [receive payments from \_\_\_\_\_\_\_\_, Inc. for \_\_\_\_\_\_] [hold stock in\_\_\_\_\_\_\_\_\_\_, Inc.], the company sponsoring the study whose product is the subject of this study. Because of these interests, Dr. \_\_\_\_\_\_\_\_\_\_ [and Dr. \_\_\_\_\_\_\_\_\_] may each benefit financially from the outcome or success of this study. HSS’s Conflict of Interest Committee has reviewed the potential conflict related to the doctors’ financial interest in \_\_\_\_\_\_\_\_\_\_\_, Inc.

As part of the effort to reduce the potential for this financial interest to influence the conduct of this study or the analysis of the results of this study, HSS will require that in any publication of the study results, Dr. \_\_\_\_\_\_\_\_\_\_\_ [and Dr. \_\_\_\_\_\_\_\_] disclose the fact that each of them had a financial interest in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ during the time of this study.

If you have questions about the financial interest of Dr. \_\_\_\_\_\_\_\_\_ [or Dr. \_\_\_\_\_\_\_\_\_\_\_] in \_\_\_\_\_\_\_\_\_\_, Inc., you may ask Dr. \_\_\_\_\_\_\_\_\_[ or Dr.\_\_\_\_\_\_\_ ]to explain it to you. HSS requires its physicians to answer your questions about significant financial interests they hold which are related to studies done at HSS. However, if you are not comfortable discussing this matter with Dr. \_\_\_\_\_\_\_\_\_\_ [or Dr. \_\_\_\_\_\_\_\_\_\_], you may contact the Vice President of Research at (212) 774-2394 to discuss the financial interest or any other information about the HSS’s conflict of interest process that you may want to know about before deciding to participate in this study. You may also contact HSS’s Office of Legal Affairs at (212) 606-1592 if you have any questions regarding the disclosure process described above. If, because of the potential for conflict of interest, you choose not to participate in this study, you can withdraw, and you can choose to continue with other treatments at HSS.

1. **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 provide you compensation or reimbursement for 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.

1. **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, <INVESTIGATOR> can be reached at <NUMBER> during office hours and at <NUMBER> after business hours.

[The <co-investigator> at <LIST THE SATELLITE SITE(S)> can be reached at <NUMBER> during office hours and at <NUMBER> 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 HSS Institutional Review Board at (212) 774-7123.

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]](#footnote-2)Signature of Parent/Legal Guardian Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Print Name of Person Obtaining Consent Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

As an HSS representative, and the person obtaining consent, 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 ELECTRONIC MEDICAL RECORD**.

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. [↑](#footnote-ref-2)