### INFORMED CONSENT TO PARTICIPATE IN RESEARCH (Observational and/or Radiological 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 that the entity that supporting the 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 may be coming from an outside company. That outside company funding the HSS study would be listed in “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 is not 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 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. ***WHY IS THIS STUDY BEING DONE*?**

The purpose of this study is to determine <XXXXX>.

A total of <XX> subjects will participate in this study at HSS.

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.

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.

***F. 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 | 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.

<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 REMOVE THE ALTERNATIVE THAT IS NOT APPLICABLE – WHEN THE STUDY OR A SPONSOR/FUNDER IS PAYING FOR SOME COSTS BUT NOT PAYING FOR THE SUBJECT’S CO-PAYS, DEDUCTIBLES, ETC., THE FIRST ALTERNATIVE SHOULD REMAIN AND THE SECOND SHOULD BE REMOVED>

**<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.”>

(**OPTIONAL PHOTOGRAPH SECTION:** <**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 these will be photographs or video>**

These images will be shared with: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ <**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 will 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 will be scrambled and obscured to protect your identity.

1. PREGNANCY. **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 or individual taxpayer identification 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>

* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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<**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 Outside HSS of Certain Private Health Information that More Directly Identifies you to Accomplish the Study (“Highly Identifiable Information”):** **:<Drafting Note:** remove the information that will not be shared outside HSS**>**

**Private health information may include the following Highly Identifiable Information which may be be disclosed outside of HSS 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 [Option1: “you must”] [“you do not need to”] agree to the disclosure of the above Highly Identifiable Information. [Goes with Option 1: “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(s) or entity(s)*] to be used solely to accomplish this study. I do not give [*enter name of recipient institution(s) or entity(s)*] 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 disclose the Highly Identifiable Information listed above for this study. . I understand that my other private health information listed above will still be disclosed outside HSS. [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, other than the Highly Identifiable Information listed above, to the people and organizations listed below to accomplish this study. Highly Identifiable Information will be disclosed solely as described above.

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, 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, Memorial Sloan-Kettering Cancer Center, HSS-Florida Physicians LLC. <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. To withdraw your participation from the study, you may provide oral or written notification to the Principal Investigator using the address provided above or by phone at the number listed in Section 15, below].**

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 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.

1. SOURCE OF FUNDING

Funding for this study will be provided by <SPONSOR> (or if applicable, and/or <DEPARTMENTAL FUNDS>.)

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.

**By signing this consent, you also are acknowledging that you have received a copy of the HSS Notice of Privacy Practices. This Notice also is available at the following website: https://www.hss.edu/notice-of-privacy-practices.asp**

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

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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)