|  |  |
| --- | --- |
| **Project Title:** |  |
|  |  |
| **Research Project/Protocol #:** |  |
| **Principal Investigator:** |  |
| **Arm/Group** | *(If there is more than one consent for the study, please indicate the type of consent here (E.g., Screening Consent; Group B Consent), otherwise, delete row.* |
| **Subject Name or number:** |  |
| **MRN** | *If you will not be obtaining the MRN, please delete this row* |

**Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.**

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

**INSTITUTION: [Institution Name]** *(If applicable, include other institutions participating in this research under this IRB approval, including institutions that will be receiving data about the subject and/or locations to which subjects will have to travel for research)*

**INTRODUCTION**

You are invited to participate in a research study. You were selected as a possible participant in this study because (*state why and how the subject was selected*).

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

1. Taking part in the study is entirely voluntary.
2. If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits to which you are entitled.
3. Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other important information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. Please take whatever time you need to discuss the study with your physician and family/loved ones/friends. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

*(If applicable)*

***For industry, foundation, government sponsored studies:***

The research study is being sponsored by *(name of agency/company)*. *(Name of agency/company)* is called the Sponsor and [Site/Institution Name] is being paid by *(name of agency/company)*, to conduct this study. *(Name of investigator)* is the primary investigator and  *(Name of site investigator) is the investigator at this site (include site investigator if applicable).*

(*If applicable)*

***For Investigator Initiated Studies:***

The research study is being funded by *(name of agency/company)*. *(Name of agency/company)*is providing a research grant/funds and study drug (if applicable) for this study. *(Name of investigator)* is the primary investigator.

The study will take place at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [*Please indicate which part of the study will take place at each location. If there are a number of potential locations for a particular part of a study, please list (bullet) all those potential locations here. If portions of the study will take place at various locations, please include the following: “Some portions of the study may take place at [XXXX], where the investigators are members of the medical staff. [XXXX] is neither a sponsor nor an investigator for this study.”]*

**WHY IS THE STUDY BEING DONE?**

The purpose of this study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*(Choose applicable text or customize your own:)*

*Observational Studies:* Learn about the natural history of *(name of disease)* and its causes and treatments.

*Phase I Studies:* Test the safety of*(drug/intervention)* and see what effects*(good and bad)*it has in your *(patient’s condition)*.

or

Find the highest dose of *(drug)*that can be given without causing severe side effects.

*Phase 2 Studies:* Find out what effects *(good and bad)* *(drug/intervention)* has on you and your *(patient’s condition)*.

*Phase 3 Studies:* Compare the effect *(good and bad)* of the *(new drug/intervention)* with **(***commonly-used drugs/intervention)* on you and your *(patient’s condition)* to see which is better.

This research study is being done because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*[Explain in one or two sentences. Examples are: “Currently, there is no effective treatment for this type of condition,” or “We do not know which of these commonly-used treatments is better.”]*

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Participants in the study are referred to as subjects.

About \_\_\_\_ subjects will take part in this study worldwide; \_\_\_\_\_\_ subjects will be recruited at this site.

**WHAT IS INVOLVED IN THE STUDY?**

*[Provide simplified diagram, calendar of required visits, flow chart, etc. in the consent form or as an additional handout to assist subject with participation.]*

*[For randomized studies:]*

You will be “randomized” into one of the study groups: *(describe the groups)*. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers will choose what group you will be in. You will have an*(equal/one in three/etc.)* chance of being placed in any group. *(If blinded)* Neither you nor the investigator will know what group you are in but the study doctor can find out if medically necessary.

You will be given a study drug and it will either contain *(name of drug)* or placebo (pills with no study drug)

*[For nonrandomized and randomized studies:]*

If you take part in this study, you will have the following tests and procedures:

*[List procedures and their frequency or use a simple table or chart. For randomized studies, list the study groups and under each describe categories of procedures. Include whether a patient will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard .You may use simple paragraphs or charts]*

*[Briefly describe study procedures that are being done as part of regular care and may be done even if the subject does not join the study and indicate that consent for the procedure (if applicable) will be obtained as part of clinical care.]*

*[Describe standard procedures being done only because subjects are in this study.]*

*[Describe experimental procedures that are being tested in this study.]*

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

**HOW LONG WILL I BE IN THE STUDY?**

We think you will be in the study for *(months/weeks, until a certain event, etc.)*.

*[Where appropriate, state that the study will involve long-term follow-up and the expected timeframe.]*

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. If you choose to leave the study, your regular care will not be affected, nor will you lose any benefits to which you are entitled. In addition your relations with WCMC, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

*[Describe any serious consequences of sudden withdrawal from the study.]*

**Withdrawal by investigator, physician, or sponsor**

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**WHAT ARE THE RISKS OF THE STUDY?**

For trials of [drugs/devices/procedures (Choose as appropriate)], there may be risks. These risks will be discussed with you by the research doctor and/or your regular doctor.

Risks and side effects related to the [drugs/devices/procedures (Choose as appropriate; do not include the risks of procedures that are being done as standard of care, or only summarize briefly)] we are studying include:

*[List by regimen the physical and nonphysical risks of participating in the study in categories of “very likely” and “less likely but serious.” You may choose instead to classify risks as “likely”, “possible”, or “rare.” Nonphysical risks may include such things as the inability to work. Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening.]*

There may also be side effects, other than listed above that we cannot predict. Other drugs may be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the *(drug /intervention)* is stopped, but in some cases side effects can be serious, long lasting or permanent.

*[For studies involving imaging studies being done for research purposes only, please include the following]:*

(*Insert names of appropriate imaging study(ies) here*) studies might involve unsuspected, incidental findings that might or might not be a sign of disease and might or might not lead to further medical work-up. This further medical work-up (if it is performed) might have associated risks, potentially cause anxiety, and may incur costs to you and/or your insurer.

*[Observational studies – describe risks and discomfort of procedures and questionnaire.]*

For more information about risks and side effects, ask the researcher or contact\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*[Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks.]*

#### **Considerations for Pregnancy and Sexual Activity (if applicable)**

*[Provide any information on contraception, barrier use and pregnancy testing requirements for the study. Explain what should occur if they or their partner become pregnant while participating in the study. Include a statement regarding unknown risk and/or specific risk that may occur if subject or partner becomes pregnant, is pregnant or is breast-feeding, etc.]*

*[For studies involving imaging being done for research purposes only, please include the following]:*

If there are any unsuspected, incidental laboratory or pathological findings that you should know about, the Principal Investigator will share the findings with you or a physician who you may designate. Incidental findings noted on the (*insert names of appropriate imaging study(ies) here*) study might or might not have clinical significance and might or might not lead to further medical tests or treatments. It will be up to you and your designated physician to determine if any further testing or treatment is necessary on the basis of this information*. (The following italicized text is optional and could be inserted if the study performed as part of the research protocol is indeed a limited MRI / imaging examination to the extent that the statement is appropriate. This should be determined in conjunction with the department providing the imaging study prior to submission to the IRB.)* *However, you should know that the limited MRI/imaging that is done in conjunction with this study is not meant to be a comprehensive examination, therefore we may not detect abnormalities or diseases which may be present and might be detected in a full clinical and diagnostic MRI examination. Should we find abnormalities in our limited MRI examination of your brain, your doctor might recommend that you undergo the full diagnostic MRI, which would then no longer be considered a part of this study.*

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

We cannot and do not guarantee that you will receive any benefits from this study. *[Add any appropriate language. Additional language may include:* We hope the information learned from this study will benefit other patients with {insert condition under study**}** in the future.*]*

**WHAT OTHER OPTIONS ARE THERE?**

Instead of being in this study, you have these options:

*[Describe and/or list the alternative options, including commonly used therapy(ies) or disclose standard diagnostic procedures or treatment being withheld.]*

You may choose not to participate in this study.

**WHAT ABOUT CONFIDENTIALITY?**

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medial record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

[*Please remove any organizations that do not apply to this research and add any additional organizations*].

* [Site/Institution Name]
* The WCMC Institutional Review Board (IRB)
* The Office of Human Research Protection (OHRP)
* Department of Health and Human Services
* National Institutes of Health
* LIST other federal funding agencies
* The Food and Drug Administration (FDA) and/or their representatives
* INSERT SPONSOR/COMMERCIAL ENTITY and/or their representative (insert name of CRO if applicable) will have access to your files.

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to [Site/Institution Name] by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: [*State here whether you are keeping data on a computer that will identify the subjects in the study. If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room, is it art of a network, is a password required for getting onto the system, who has access to these data, etc.].* In addition, only personnel who are associated with the study will have access to the study specific records in the database.

*[If this clinical trial is registered on ClinicalTrials.gov, please include the following statement in the confidentiality section of the informed consent.]*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

**Purposes for Using or Sharing Protected Health Information:** If you decide to join this study, [Site/Institution Name] researchers need your permission to use your protected health information. If you give permission, [Site/Institution Name] researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

**Voluntary Choice:** The choice to give [Site/Institution Name] researcher’s permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for [Site/Institution Name] researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from [Site/Institution Name].

**Protected Health Information To Be Used or Shared:** Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes*[You must list all categories of tests and diagnostic procedures including but not limited to Genetic testing, HIV testing, and Hepatitis testing must be specifically listed if applicable].*

**Other Use and Sharing of Protected Health Information**: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with *[name all persons or groups including collaborating researchers or teams at other institutions (naming the institution), labs and consultants, as well as other groups of individuals who may have access to protected health information in this study]***.**

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

**Use of Psychotherapy Notes [IF NOT APPLICABLE, YOU MAY DELETE THIS SECTION]**

**What are Psychotherapy Notes for Research? [IF NOT APPLICABLE, YOU MAY DELETE THIS SECTION]** [Site/Institution Name] may use or share (disclose) information about you from the doctor’s notes about your psychotherapy sessions for this study that is considered to be protected health information.

**Future Research [THIS SECTION MUST BE INCLUDED FOR ALL STUDIES COLLECTING OR STORING DATA/SAMPLES FOR FUTURE RESEARCH. IF NOT APPLICABLE, YOU MAY DELETE THIS SECTION]**

You may agree to allow your data, and/or sample(s) (tissue, blood, urine, etc.) to be used for future research within [Site/Institution Name] or at outside institutions and private companies. If information goes to an outside entity then [Site/Institution Name] cannot ensure the privacy rule is followed.

**RESEARCH REPOSITORY [ONLY APPLICABLE TO STUDIES THAT INTEND TO KEEP DATA/SAMPLES FOR FUTURE RESEARCH AS A SECONDARY PURPOSE]**

**What is a Research Repository?** A research repository (database) is a collection of information from the health and medical records of many individuals and can sometimes include identifiable specimens (like your tissue). The repository (database) may share the information with researchers who study medical conditions and diseases.

The repository (database) includes codes that identify each person whose information is collected. However, the repository does not share information with researchers unless the researchers promise to keep the information confidential.

**RESEARCH PARTICIPANT: Please check the box below that describe your wishes:**

The [indicate whether sponsor or Site/Institution Name] Repository may keep my protected health information and/or specimens and share it with qualified researchers studying the research described above. If information goes to an outside entity then the Privacy Rule may not apply.

The [indicate whether sponsor or Site/Institution Name] Repository may keep my protected health information and/or specimens and share it with qualified researchers studying the research described above **AND** for unspecified research to be done in the future. I understand that the samples will be stored for \_\_\_\_\_ [*Investigator fill in number*] years and will be destroyed after the research is completed. If information goes to an outside entity then the Privacy Rule may not apply.

The [indicate whether sponsor or Site/Institution Name] Repository may not keep my protected health information for a research repository.

*[Please add the following sentences if this study will involve obtaining specimens that will be stored at* Site/Institution Name] *(i.e., a* Site/Institution Name *sponsored tissue bank). This does not apply if the Tissue Bank will not be sponsored by* Site/Institution Name*]*

By signing this consent form, you agree to give these samples to [Site/Institution Name] for research purposes.

*[If genetic analysis will be performed on the specimens, please include information from the informed consent for genetic testing in this informed consent, or submit the Informed consent for Genetic Testing as part of the protocol submission.]*

**CANCELING AUTHORIZATION**

**Canceling Permission:** If you give the [Site/Institution Name] researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office

1300 York Avenue, Box 303

New York, NY 10065

Email: [privacy@med.cornell.edu](mailto:privacy@med.cornell.edu)

If you have questions about this and would like to discuss, call (646) 962-6930.

**End of Permission:** Unless you cancel it, permission for [Site/Institution Name] researchers to use or share your protected health information for their research will never end.

**ACCESS TO RESEARCH RECORDS (Choose the language below that applies to the protocol)**

During the course of this study, **you will have access** to see or copy your protected health information as described in this authorization form in accordance with [Site/Institution Name] policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

**OR**

During the course of this study**, you will not have access** to see or copy certain parts of your protected health information that contains research information as described in this authorization form, in accordance with [Site/Institution Name] policies. This is done to prevent knowledge of study results affecting the reliability of the study. The part of your private information that you will not have access to is/are: *[name the specific part(s)/test(s) of the research record that subjects temporarily will not have access to].* Your information will be available should an emergency arise that would require the treating physician to know this information in order to best treat you. Your right to access this information will be reinstated when*[insert a specific time frame, such as ‘initial treatment is complete’ or ‘follow-up is complete’].* If youwish to appeal this temporary suspension at any time, please write to the Privacy Officer at the address on this form. By signing this form, you are agreeing to this temporary suspension of your rights to access protected health information.

**CERTIFICATE OF CONFIDENTIALITY**

**[THIS SECTION MUST BE INCLUDED FOR ALL NIH-FUNDED STUDIES COLLECTING/USING IDENTIFIABLE INFORMATION. Refer to:** [**https://humansubjects.nih.gov/coc/NIH-funded**](https://humansubjects.nih.gov/coc/NIH-funded)**]**

**(\* NOTE: THIS IS ONLY AN INSTRUCTION FOR THE PI - DO NOT INCLUDE THIS SECTION IF IT DOES NOT APPLY TO YOUR STUDY\*; SENSITIVE INFORMATION INCLUDES (BUT IS NOT LIMITED TO) INFORMATION RELATING TO SEXUAL ATTITUDES, PREFERENCES, OR PRACTICES; INFORMATION RELATING TO THE USE OF ALCOHOL, DRUGS, OR OTHER ADDICTIVE PRODUCTS; INFORMATION PERTAINING TO ILLEGAL CONDUCT; INFORMATION THAT, IF RELEASED, MIGHT BE DAMAGING TO AN INDIVIDUAL'S FINANCIAL STANDING, EMPLOYABILITY, OR REPUTATION WITHIN THE COMMUNITY OR MIGHT LEAD TO SOCIAL STIGMATIZATION OR DISCRIMINATION; INFORMATION PERTAINING TO AN INDIVIDUAL'S PSYCHOLOGICAL WELL-BEING OR MENTAL HEALTH; AND GENETIC INFORMATION OR TISSUE SAMPLES.)** A Certificate of Confidentiality has been granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (research/study staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. For instance, it does not override any state requirement to report child abuse to the appropriate authorities.

**WHAT ARE THE COSTS?**

You [will/will (please choose as appropriate)] not have to pay for the study drug/treatment. You or your insurance company will have to pay for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*Note to Researchers: Be as specific as possible about additional costs. Be careful to complete this language in a manner consistent with the WCM HRBAF or your institution’s research billing process. Subjects should only be told that they will have no costs for specific services (tests, procedures, exams, etc.) if those services are listed on the HRBAF as being billed to the study or the sponsor. If services are listed on the HRBAF as being billed to the patient or insurance company, subjects must be informed here that the costs for the relevant services will be billed to their insurance company and that they will be responsible for any costs not covered by their insurance or by the Sponsor, if applicable.*

Example of template language: The study drug, XXXXX, will be provided free of charge by Insert SPONSOR. (*If administration of the study drug is required* The cost of study drug administration will be billed to you or your insurance provider). The costs of all of the other medications and the administration of these medications that you receive during this study will be charged to you or your insurance provider. The sponsor/study will also pay for any study related procedures that are not considered standard care for patients with your disease. These include XX and YY. (You can get this information from the billing compliance form)

(For this section, please reference the procedures section of the ICF). The physical examinations, standard laboratory tests, radiographic evaluations, and diagnostic procedures such as the CT scans involved in this study, are considered part of the standard care for patients with your disease.  The costs associated with each test will be charged to you or your insurance provider in the same manner as if you were not part of this research study.  Therefore, you or your insurance provider will need to assume responsibility for these costs.   You will be billed for all costs or co-payments that are not paid by your insurance provider.

(Include this paragraph if applicable) Taking part in this study may lead to added costs for you or your insurance company. Please ask about any expected added costs or potential insurance problems. You may wish to consult with your insurance company in advance about whether insurance will pay for these costs.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

*[For studies involving imaging studies being done for research purposes only, please include the following]:*

If unsuspected, incidental findings are noted in the review of the (*insert names of appropriate imaging study(ies) here*) study and further medical tests and/or treatments are considered, such tests and/or treatments are no longer considered part of the study and therefore would be billed to you or your insurer. You should expect no compensation or reimbursement for these costs or any risks and anxieties associated with any such follow up care. You or your insurance company will also be charged for any continuing medical care and/or hospitalization that are not a part of the study.

**POLICY/PROCEDURES FOR RESEARCH RELATED INJURY**

**The Policy and Procedure for the Sponsor are as follows:**

[Include the Sponsor’s statement here---the Sponsor, (identify by name), will or will not pay for care necessitated by a research related injury. If the Sponsor will pay such costs, Medicare/Medicaid cannot be primary payors. If applicable, the language in this section must track the language in the Clinical Trial Agreement with the Sponsor. Please contact the contracts office at [JCTOcontracts@med.cornell.edu](mailto:JCTOcontracts@med.cornell.edu) with any questions. The following is acceptable language if the Sponsor specifies that it will only pay costs not otherwise covered by insurance:]

If you suffer a research related injury, the Sponsor will pay for medically necessary items or services for the diagnosis and treatment of the Research Related Injury as described below:

(1) If you have private health insurance, the Sponsor will pay for the costs that are denied or not otherwise paid for by your insurance company.

(2) If you do not have any health insurance, the Sponsor will pay for the costs; and   
  
(3) If you have Medicare or Medicaid, claims for the costs will first be submitted to the Sponsor for payment, and any remaining balance not paid for by the Sponsor will be submitted to Medicare or Medicaid, subject to applicable Medicare and Medicaid billing rules and regulations.

[Additional optional language to be used if this language is included in the Clinical Trial Agreement with the Sponsor:]

The sponsor will only pay for research related injuries if the study was properly performed. The sponsor will not pay for injuries resulting from your pre-existing condition unless that condition was made worse by the study drug or the study procedure.

Medical expenses will not be reimbursed if the Research Related Injury is the result of your intentional failure to follow instructions in this consent form or instructions communicated by study personnel or it is the result of the natural progression of an underlying or pre-existing condition.

**The Policy and Procedure for** [Site/Institution Name] **are as follows:**

We are obligated to inform you about [Site/Institution Name]’s policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from [Site/Institution Name]. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

**COMPENSATION FOR PARTICIPATION**

You *[will/will not]* receive compensation for participating in this study*. (State payment method, schedule and amount. Some examples are provided below)*

*If paying by check:* You will receive a stipend of [insert dollar amount] for each completed study visit. This will be paid to you in the form of a check approximately six weeks after you complete the study.

*If you will be utilizing ClinCard for stipends:* You will receive a stipend of [insert dollar amount] for each completed study visit. This will be paid to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 5 business days after you complete your study visit. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.

*To be included if subjects are receiving payments (excluding reimbursements):*

Your personal information, including name, address, and social security number, will be released to the Finance Department of [Site/Institution Name] for the purpose of payment, as well as for reporting to the Internal Revenue Service if total payments for the calendar year (excluding reimbursements) exceed 600.00 dollars.  You will be asked to complete IRS form w9 for this purpose. At the end of the tax year, [Site/Institution Name] will use this information to provide you with Federal Form 1099-MISC, Miscellaneous Income, listing your payment as reportable income, if applicable. If you do not complete the w9 form, you may participate in this study, but you will not receive any payments for participating in this study.

*If subjects are receiving reimbursements:* You may be eligible to receive reimbursement of your travel expenses, depending on the distance you travel to come to [Site/Institution Name]. You will be required to provide the study coordinator with receipts of your travel expenses. Please ask the researchers for additional information. You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study. *If providing reimbursement by check:* Your reimbursement will be paid to you in the form of a check approximately six weeks after you submit your receipts. *If you will be utilizing ClinCard for reimbursement:* Your reimbursement will be paid to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 5 business days after you submit your receipts. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.

**COMMERCIAL INTEREST** *(if applicable)*

*Note to investigator: If anyone involved in the study has a financial interest related to this study, please include a statement using the appropriate language from the choices below.*

Materials or data obtained from you in this research may be used for educational or commercial purposes. It is the policy of [Site/Institution Name] [and the Sponsor, if applicable] not to provide financial compensation to you should this occur.

* Licensing of materials: Any data and samples you donate which is used in research may result in new products, tests, or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the researchers, [Site/Institution Name] and/or others (e.g., private companies). However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.
* For Consulting, etc: Dr. X, [*role in the study - choose PI or Co-investigator*], serves as a [paid, unpaid] [*use CONSULTANT for any of the following relationships - consultant, member of the Speakers Bureau, Advisory Board member, etc*] for [*the sponsor, the name of the company whose product is being used or tested, etc*]. [*State the relation of the company to the research if that would add valuable information.*]
* Equity ownership: *Dr. X, [role in the study], [owns stock, has an equity ownership]* in *[the name of the entity and its relation to the research - e.g., the sponsor of the study, the company that markets the drug being used, etc]*.
* Royalties: *Dr. X, [role in the study],* receives royalties from *[the name of the entity and its relation to the research]*.
* Patents or patent applications: *(Name of institution or individual investigator)* holds a patent *[or has applied for a patent or is an inventor (whatever applies)]* for this *[device or drug]* and has a potential financial interest in the outcome of this study.

If you have any questions or would like additional information about the financial interests described in this paragraph, please contact [institution office or contact information] at [XXX-XXX-XXXX].

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with [Site/Institution Name], your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

*[Please include the following when a Data Safety and Monitoring Board exists:]*

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call *(name)* at *(telephone number)* or the [*Department name, e.g., Neurology*]. Be sure to inform the physician of your participation in this study.

[Note to Researchers: Please note that this must be a 24 hour telephone number. The on-call number should be provided in addition to the PI’s number.]

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:

(646) 962-8200

1300 York Avenue

Box 89

New York, New York 10065

**RESEARCHER’S STATEMENT**

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual’s satisfaction.

Signature of person obtaining the consent Print Name of Person Date

(Principal Investigator or Co-investigator)

**To be used when consenting Non-English Speaking Subjects using a Translated Short Form Consent**

**NOTE: NYP Interpreters cannot serve as a witness for studies.**

In case the patient/legal representative does not speak English, an official interpreter has been informed about the purpose, procedures, benefits, risks of and alternatives to the proposed research project and has told the subject/legal representative everything pertaining to her participation in this study and verifies this by signing below.

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Interpreter’s Name (Print) Interpreter’s Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_

Name of Person Present (Print) Signature of Person Present Date

During Oral Presentation During Oral Presentation

**SUBJECT’S STATEMENT**

I, the undersigned, have been informed about this study’s purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with *(name of principal investigator)* and the research staff and to inform them immediately if Iexperience any unexpected or unusual symptoms.

Signature of Subject Print Name of Subject Date

(NOTE: Signature lines should not stand alone on a page, without preceding text)

In case needed, also add signature line for parent and/or include the following section:

**LEGALLY AUTHORIZED REPRESENTATIVE**

**[TO ONLY BE USED FOR STUDIES THAT IRB APPROVED USE OF LAR]**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on behalf of the research project participant, signed above, have been fully informed of the purpose, benefits, risks of and alternatives to the proposed research project and as his/her legal representative consent to his/her participation in this research project. I have also been informed on the ways in which his/her protected health information will be used and disclosed in connection with participation in the project described above.

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

Signature of Legally Authorized Representative or Healthcare Proxy Date

and Relationship to Participant (When Appropriate)