**UNIVERSITY OF MIAMI**

Rec’d by NMDP IRB on 10/02/2019

**BOILERPLATE CONSENT LANGUAGE**

**LOCAL CONTACT INFORMATION**

**[…] RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

|  |  |
| --- | --- |
| **TITLE:**  | […] |
|  |  |
| **Protocol No.:** | [Sponsor’s Protocol #]UMeProst # […] |
|  |  |
| **SPONSOR:** | [Sponsor’s Name] |
|  |  |
| **Investigator:** | [Principal Investigator Name], MDUniversity of Miami – Sylvester Comprehensive Cancer Center1475 NW 12th AvenueMiami, Florida 33136United States |
|  |  |
| **STUDY RELATED PHONE NUMBERS:** | [Principal Investigator Name], MD**[**Daytime Telephone Number] (Office)**[**24-hr Number] (24-Hour) |

**CONFIDENTIALITY**

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of Miami representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. [Include any/all of the following three statements as appropriate, deleting those which do not apply.

* We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data.
* We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.
* The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data and link between the code and your identity will be kept at the research site.

We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. Information which can identify you may be removed from the data or samples we collect, and after such removal, the data or samples could be used for future research studies or provided to another researcher for future research without additional informed consent.

The following is a list of individuals who may access your records:

* Members of the research team
* Offices and committees responsible for the oversight of research
* Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
* The U.S. Food and Drug Administration (FDA)
* Regulatory Authorities from other countries
* The study sponsor
* Collaborating researchers outside of the University of Miami, including researchers at [name collaborating institutions]
* Companies or groups performing services for the research team
* [For federally funded studies only, include the funding agency and:] U.S. Office for Human Research Protections

The study doctor and research team may publish the results of this research. However, they will keep your name and other identifying information confidential.

**Access to** **UChart (electronic medical record)**

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in UChart. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are on this study.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

**AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION**

Federal law provides additional protections of your medical records and related health information. These protections are described in the University of Miami HIPAA authorization for research known as a Form B. You will be asked to review and sign a HIPAA (Health Insurance Portability and Accountability Act) Research Authorization Form requesting your authorization to collect, use, and disclose your medical information.

**WHERE CAN I GET MORE INFORMATION?**

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

**GENETIC TESTING** *–* ***[Language is added only if applicable.]***

This study also involves genetic testing. Genes control how your body grows and changes, and how your body reacts to certain things. Genes are what we get from our parents that help make our bodies what they are. For example, eye and hair color depend on the genes we received from our parents. Genes are made up of DNA (deoxyribonucleic acid), which can be collected from blood, saliva, or other tissue samples. We want to find out how genes work in [name the disease or condition]. It may be true that some people are more likely to have [describe the disease or condition] because of their genes and we would like to learn more about this.

We [will/will not] tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene that makes it more likely that you will have a health problem. However, that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

[Include if applicable] No one will know that the [blood/ tissue] sample came from you. Since we did not link your name or other identifying information to the [blood/ tissue] sample, once you agree to allow us to use it, you cannot change your mind. We will not be able to find your sample to remove it from all the others we collect. Once the sample is provided, it is forever separated or “unlinked” from your identifying information to protect your privacy. When this occurs, the researchers will not be able to provide you with information discovered from your sample. If you are concerned about a possible genetic disease or problem, you may want to ask your study doctor whether you can have a separate test done specifically for this. You should discuss this option with your study doctor or a genetic counselor. Even though your name will not be connected with the tissue or blood sample, other information about you might still be connected. Examples of this information may be your race, ethnicity, or parts of your medical history. This information may be important to scientists studying genes. The information they discover may be important for research or for public health.

**GINA** – *required if genetic testing is done (regardless of whether language is separate or in Main ICF)*

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, group health plans, and employers as outlined above must follow this law. Please note that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**HIV AND** **HEPATITIS B / C TESTING RISKS** *–* ***[Language is added only if applicable.]***

As part of the study you will be tested for [HIV / Hep B / Hep C, as applicable]. Florida regulations require health care providers/laboratories to report new cases of HIV, AIDS, hepatitis infection and some STD to the county health department. If you test positive for [HIV / Hep B / Hep C, as applicable], by law we have to report the personal identifiers such as name, sex, date of birth, address and phone number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be kept confidential to the extent permissible under the law. The health department may contact you with resources for counseling and medical care, if you need them and want them.

**CT (COMPUTED TOMOGRAPHY) SCAN RISKS** *–* ***[Language is added only if applicable.]***

If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments include a whole body CT scan. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. Each scan in this research gives your body the equivalent of about 3 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received, or will receive, from other tests.

In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, which may cause symptoms ranging from mild itching, or a rash, to severe difficulty breathing, shock, or rarely, death. The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan.

**CLINICAL MRI (MAGNETIC RESONANCE IMAGING) RISKS** *–* ***[Language is added only if applicable.]***

The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips, and pacemakers. Tell the doctor if you have or may have any metal items within your body.

MRI scanning is painless but you might experience discomfort in the machine. In particular, loud beeping and hammering noises occur during the study when the scanner is collecting measurements. You also may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. You might also experience stimulation of the nerves in your body, which feels like a gentle tap or sensation of mild electric shock.

Because the risks to a fetus from MRI are unknown, you cannot participate in this study if you are pregnant.

*Injection of Gadolinium during Clinical MRI***:** Gadolinium, a substance given during the MRI examination, will be given by injection into a vein in your arm. This may cause some minor pain, and may cause some bruising near the area of injection. Gadolinium may also cause headache, nausea, and vomiting. Rarely, it may cause dizziness, rash, itching, or a numb or tingling feeling in the hands or feet, or an allergic reaction. Medical personnel will be available to treat any of these problems if they should occur.

*Nephrogenic Systemic Fibrosis Risk Associated with Gadolinium***:** Some people who have had MRIs with gadolinium-based contrast agent gadodiamide have experienced a serious reaction called nephrogenic systemic fibrosis (NSF). NSF is a condition where people develop large areas of hardened skin with lesions called plaques and papules with or without skin discoloration. In some cases, NSF could lead to physical disability and may involve not only the skin, but also the liver, lungs, muscles, and heart. The typical patient in whom this has occurred is middle-aged and has end-stage kidney disease.

*Potential Risks of Neuronal Tissue and Bone Deposition of Gadolinium***:** Recent studies have shown that small amounts of gadolinium may be deposited in your neuronal tissue (brain, spinal cord and nerves) and bones. This deposit appears to accumulate over your lifetime, and happens without associated renal (kidney) or hepatobiliary (liver and gallbladder) problems. Neuronal and bone tissue deposits appear to take place in all patients exposed to gadolinium and can be found in people after as few as four doses. The importance of these findings is not completely understood. No long-term effects have yet been seen, but may be found in the future.

**PET (POSITRON EMISSION TOMOGRAPHY) SCAN RISKS** *–* ***[Language is added only if applicable.]***

If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a PET FDG scan. To give you an idea about how much radiation you will get, we will make a comparison with an everyday situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. Each scan in this research gives your body the equivalent of about 6 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received, or will receive, from other tests.

**MUGA (MULTIPLE GATED ACQUISITION) SCAN RISKS** *–* ***[Language is added only if applicable.]***

If you take part in this research, you will have one or more medical imaging studies which use radiation. The tests or treatments you will have include a MUGA scan. To give you an idea about how much radiation you will get, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. Each scan in this research gives your body the equivalent of about 2 extra years' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received, or will receive, from other tests.

**Chest X-Ray Risks** *–* ***[Language is added only if applicable.]***

If you take part in this research, you will have one or more medical imaging studies or treatments. The tests or treatments you will have include chest x-rays. These tests or treatments involve a small amount of radiation. To give you an idea about how much radiation you will get, we will compare it to the amounts that people encounter in daily life. There is radiation that naturally occurs from space and from rocks in the soil. This natural radiation is greater at higher altitudes. Each chest x-ray for this research gives you about the same amount of radiation as you would get from living in a high altitude city such as Denver for 12 days, or taking 4 airplane flights from New York to Los Angeles. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests.

**BIOPSY RISKS** *–* ***[Language is added only if applicable.]***

If a biopsy is performed, there may be some pain or bruising from the procedure. Biopsies are normally performed under the guidance of an imaging technique.

The type of biopsy and the specific risks associated with the procedure will depend on the location of your tumor. At the time of the procedure, you will be presented with a Procedure Consent to sign, and the specific technique and risks will be discussed with you.

The risks may include, but are not limited to:

* Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
* Minor bleeding at the biopsy site.
* Tenderness at the biopsy site.
* Scarring at the biopsy site.
* Rarely, an infection at the biopsy site.
* If you have a biopsy from the lung, you could also have something called a pneumothorax. This is where air escapes between the lung and the chest wall.
* Complications from biopsies including bleeding or infection could lead to:
	+ the need for further treatment,
	+ blood transfusions, or
	+ hospitalization with extra procedures

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

**COMPENSATION FOR INJURY** *–* ***[Language added as applicable.]***

*Sponsored studies that involve greater than minimal risks:*

If you are hurt or get sick as a result of being in this study, treatment will in most cases be available. If you experience an injury as a result of the study drug or procedures, the Sponsor will cover the cost of treatment of these injuries. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system. [Include if applicable, otherwise delete.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

*Non-Sponsored studies that involve greater than minimal risks:*

If you are hurt or get sick as a result of being in this study, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system

**CONFLICT OF INTEREST** *–* ***[Language is added only if applicable.]***

Dr. [full name] is a sub-investigator of this study and has disclosed that [s/he], [his/her] spouse and/or dependent children have a personal interest related to the study. Please ask any questions to assure yourself that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact the study doctor or HRSO at 305-243-3195 to ask questions or discuss concerns.

If you have any questions regarding disclosure review and the conflict management process at the University of Miami, please call 305-243-0877.

**Notification/Consent for Collection and** **Use of Study Data** *–* ***[Language is added only if applicable.]***

This research will collect data about you that can identify you, referred to as Study Data. The General Data Protection Regulation (“GDPR”) requires researchers to provide this Notice to you when we collect and use Study Data about people who are located in the European Union or in the European Economic Area.

We will obtain and create Study Data directly from you or from [insert the data sources, including repositories, collaborators, publicly available sources, etc.] so we can properly conduct this research. As we conduct research procedures with your Study Data, new Study Data may be created.

The Research Team will collect and use the following types of Study Data for this research:

* Contact Information
* Health information
* Information about your response to the research procedures
* Genetic data

The Research Team will enter data about you and your health into a computer and a computer program will help the study team decide if you meet requirements to be in this study.

[Include, if applicable, otherwise delete.] The research protocol requires the Research team to enter data about you and your health into a computer. A computer program will be used to assign you to one of the following specific study treatments: [list study treatments]. If you sign this consent form, you are consenting to the use of this automated process to determine the treatment you receive.

**Please initial one of the boxes** **below** to indicate whether you consent to use of the automated processes described above.

I agree \_\_\_\_\_\_\_\_\_ I do not agree\_\_\_\_\_\_\_

This research will keep your Study Data for [insert the time the data will be maintained by the research] after this research ends.

The following categories of individuals may receive Study Data collected or created about you:

* Members of the research team so they properly conduct the research
* University of Miami staff will oversee the research to see if it is conducted correctly and to protect your safety and rights
* The research Sponsor who will monitor the study and analyze the data
* Agents of the Sponsor who will assist the sponsor with data monitoring and analysis
* Representatives of the U.S. Office of Human Research Protections (OHRP) who oversee the research
* Representatives of the FDA who will use the data to determine whether a marketing application for the investigational [drug/device] can be approved
* Other researchers, so they can perform procedures required by this research
* Other researchers, including researchers in other countries, so they can conduct additional research on [condition] and other, unrelated diseases and problems

[Include, if applicable, otherwise delete.] The research team will transfer your Study Data to our research site in the United States. The United States does not have the same laws to protect your Study Data as States in the EU/EEA. However, the research team is committed to protecting the confidentiality of your Study Data. Additional information about the protections we will use is included in this consent document.

The GDPR gives you rights relating to your Study Data, including the right to:

* Access, correct or withdraw your Study Data; however, the research team may need to keep Study Data as long as it is necessary to achieve the purpose of this research
* Restrict the types of activities the research team can do with your Study Data
* Object to using your Study Data for specific types of activities
* Withdraw your consent to use your Study Data for the purposes outlined in this consent form (Please understand that you may withdraw your consent to use new Study Data but Study Data already collected will continue to be used as outlined in this consent document and in this Notice)

The Regents of the University of Miami is responsible for the use of your Study Data for this research. The University of Miami Privacy Officer is Helenemarie Blake-Leger, Esq. You can contact Ms. Blake by phone at +1 (305) 243-5000 or by email at hblake@miami.edu. You can contact the Privacy Officer if you have:

* Questions about this Notice,
* Complaints about the use of your Study Data, or
* If you want to make a request relating to the rights listed above.

**May we contact you by** **e-mail?**

We are requesting your email address so we can contact you with study updates. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the research team. You do not have to provide your email address to participate in this study. **Please initial and date one of the lines below.**

\_\_\_\_\_\_\_\_\_\_ Yes, may use email to contact me for this study.

My email address is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_ No, I do not want to be contacted by email.

**What if i have questions?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team of Dr. [PI name, office #, and 24-hour #]*.*

This research has been reviewed and approved by an Institutional Review Board (“IRB”). The Human Subject Research Office (HSRO)provides administrative support to the University of Miami’s IRBs.

Please call the HSRO at 305-243-3195if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

**OPTIONAL SELECTIONS – the subject must initial/date next to any selections made.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  |  |  | *If yes, initial/date on the line* |
|  | No |  |  |  | *If no, initial/date on the line* |

**SIGNATURE LINES**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Participant Signature |  | Date |
|  |  |  |
| Printed Name of Participant |  |  |
|  |  |  |
| Person Obtaining Consent Signature |  | Date |
|  |  |  |
| Printed Name of Person Obtaining Consent |  |  |

**CERTIFICATE OF CONFIDENTIALITY** *–* ***[Applies only to NIH studies.]***

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

* To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
* To meet the requirements of the U.S. FDA;
* If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
* If information about you must be disclosed to prevent serious harm to yourself or others such as
* If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
* If it is used for other scientific research, as allowed by federal regulations protecting research subjects.
* To University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

**KEY INFORMATION SUMMARY** *–* ***[Applies only to NIH studies.]***

You are asked to participate in a research study. The purpose of this research is to [pick one of the following].

[For Phase I drug studies:] The purpose of this research study is to test the safety and possible harms of [drug name] when it is given to people at different dose levels. The researchers want to find out what effects (good and bad) [drug name] has on you or people with your condition.

[For Phase II drug studies:] The purpose of this research study is to see if [drug name] has any benefits at dose levels thought to be acceptable in earlier studies. The researchers want to find out what effects (good and bad) [drug name] has on you and your condition.

[For Phase III drug studies:] The purpose of this research study is to see if [drug name] is safe and effective for the treatment of your condition. The researchers want to confirm the right dose levels of [drug name] and find out what effects (good and bad) [drug name] has on you and your condition.

[For unapproved drugs, devices or procedures:]

This study involves an investigational [drug/device/procedure] that has not been approved by the U.S. Food and Drug Administration (FDA).

[For approved drugs or devices being studied off-label:] [drug/device] is a [medication/device] approved by the U.S. Food and Drug Administration (FDA) used in the treatment of [disease] and is approved for [population]. [drug/device] is used to [treatment]. In this study, however, [drug/device] is considered an investigational [drug/device] because it is not yet approved for use in the treatment [disease] or [population].

You are asked to be in this study because [briefly explain why the person is being to participate in the study, (e.g. have been diagnosed with a certain condition or meeting certain eligibility requirements)].

Your participation in this research will involve [number] visits and will last about [expected duration in hours, days, months, years]. We expect about [number] people [around the U.S./worldwide] to participate in this research.

You will be asked to [briefly provide a description of any procedures, drugs, and/or devices that the participant will experience as a part of this study].

Almost all research studies involve some risk. Risks of this study are [significant/minimal]. These risks are described in detail later in this document.

Here are some reasons you may want to participate in this research: [List the reasons a reasonable person might want to enroll such as a potential for benefit, possibility of helping others through the knowledge gained about disease/condition]

Here are some reasons you may not want to participate in this research: [List the reasons a reasonable person might not want to enroll such as a requirement for frequent visits to the research site, likelihood of receiving placebo, risks of the study, compliance with study requirements (e.g. completion of diaries, only being allowed to eat certain foods, etc.)].

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to participate or if you leave the study early.

There [are/may be] other choices available to you. These choices are listed later in this document.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

***Will I be paid or receive anything for being in this study?***

[Choose the option(s) most appropriate for your study. DELETE options that do not apply:]

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

We will pay you [dollar amount] for participating in this study. Payment will be provided at the end of the study visit in the form of ***[a gift card, cash, check, etc.]***. If you choose to leave or we take you off the study before you complete the study visit, you will receive [describe pro-rated payment].

We will pay you [dollar amount] for [Visit 1, intervention x, each study visit, etc., dollar amount for Visit 2, ***i***ntervention, etc.]. Payment will be provided[at the end of: each visit, every 3 months, the study, etc.] in the form of ***[a gift card, cash, check, etc.]***. If you complete all the study visits, you will receive [dollar amount] for being in this study. If you choose to leave or we take you off the study for any reason, you will receive [describe pro-rated payment].

You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples****]* to tell you, or to pay you, or to give any compensation to you or your family. Any blood, urine, tissue, or other biological specimens obtained for the purposes of this study become the exclusive property of the University of Miami ***[or other institution, please specify.]***

The University of Miami ***[or other institution, please specify]*** may retain, preserve, or dispose of these specimens and may use these specimens for research which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project.

**[JHS FOOTER](#Consent_Edits_Checklist)**



I read the information above (or someone read the information above to me). I had the chance to ask questions and I’m comfortable with the answers I received. My signature below means that I understand the information and that I want to take part in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Participant Signature |  | Date |
| Printed Name of Participant |  |  |

PHYSICIAN/DESIGNEE STATEMENT: I have personally explained the research to the patient or legally authorized representative and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent Signature |  | Date |
|  |  |  |
| Printed Name of Person Obtaining Consent |  |  |

WITNESS STATEMENT: I have read the consent form to the patient in a language they understand. The patient appeared to understand the information in the consent form and was given time to ask questions. The patient chose to participate in the study voluntarily by signing the consent form.

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| Witness Signature |  | Date |
| Printed Name of Witness |  |  |