**Title of Study:** *<insert title of research study here>*

**Principal Investigator:**  *<insert name of PI>*

**Department:** *<insert PI’s department>*

**Phone Number:** *<insert phone number and 24-hour contact number>*

**Email Address:** *<insert Email address>*

**Study Contact Name:** *<insert name of contact>*

**Study Contact Telephone Number:** *<insert phone number* ***and 24-hour contact number****>*

**Study Contact Email:** *<insert Email address>*

**Sponsor:** *<insert Sponsor name if applicable>*

A person who takes part in a research study is called a research or study *(****subject*/*participant***). In this consent form, “you” always refers to the research subject.

***[Include the following only if parents are consenting on behalf of their child. If the study includes adults who cannot personally consent, use the Proxy Consent Template]***

If you are the parent or guardian of a child who is participating, please remember that “you” means the child.

## Key Information about This Research Study

***[Include this section if study is or will be federally funded. The 2018 Common Rule requires a brief and concise set of statements at the beginning of the consent document that explains what a “reasonable person” would want to know about the study. This section is intended to fulfill that requirement.]***

We are asking you to join a research study. The purpose of this research is ***[provide a brief explanation of why the study is being done. Use one of the following examples, if applicable]***.

This research study aims to test the safety and possible harms of ***[drug name]*** when people receive it at different dose levels. The researchers want to find out the 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 researchers found acceptable in earlier studies. The researchers want to find out the 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].***  [***Include if FDA-regulated***]The US Food and Drug Administration (FDA) has not approved this ***[drug/device.]***

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

We are asking you to be in this study because ***[briefly explain why the person is being to participate in the study, (for example, has been diagnosed with a certain condition or meeting certain eligibility requirements]***.

If you join this research, we will ask you to come to the research site for about \_\_\_\_visits, and you will be in this study for about ***[expected duration in hours, days, months, or years]***. We expect about ***[number]*** of people ***[around the U.S./worldwide]*** will join this research.

***(Include only if you plan to include UM students)*** If you are a student, your decision not to join this study or to withdraw from the study will not affect your grades or other academic standings at the University of Miami. ***(Include only if you plan to include UM employees)*** If you are an employee of the University of Miami, your decision not to join this study or to withdraw from the study will not affect your employment at the University of Miami System.

We will ask you to ***[briefly provide a description of the main procedures, drugs, and/or devices that the participant will experience or receive 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 form.

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.)]***.

Taking part in this study is voluntary. You do not have to take part if you do not want to, and you can leave the study at any time. Whatever you decide, you will not be penalized or lose benefits.

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

The remainder of this form contains a complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether to join this study.

***What if I have Questions?***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team.]

An Institutional Review Board (“IRB”) reviewed and allowed this research to move forward. An IRB is a group of people who consider the risks and benefits of research to determine whether the research should happen. The Human Subject Research Office (HSRO) is the team thatsupports the University of Miami’s IRBs.

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

* The research team has not answered your questions, concerns, or complaints.
* 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.

*How is being in this study different from my regular health care?*

[Include this section for studies involving a patient population. Delete this section if your study does not include patients as subjects. For treatment studies, use the language below that best reflects the relationship between the study and standard care. DELETE language that does not apply:]

People with [specify the disease/condition]usually do not have any treatment until their disease gets worse. If you take part in this study, you would be taking [study drug] sooner than it is usually given to treat [disease/condition].

People with [specify the disease/condition] usually [describe standard care, e.g. have surgery/take drug]. People in this study will have [study treatment]instead.

People with [specify the disease/condition]usually [describe standard care, e.g. have surgery/take drug X]. In this study, some people will get this standard treatment, and others will get [study treatment] instead.

People with [specify the disease/condition] usually [describe standard care, e.g. have surgery/ take drug X]. In this study, some people will get this standard treatment, and others will get standard treatment and [study treatment].

There is no single standard treatment for [specify the disease/condition]. As part of their regular health care, people might get [treatment X, treatment Y, or treatment Z] or no treatment at all. People who take part in this study will all get [study treatment].

[For studies that involve research conducted concurrently with standard care, include one of the following statements. DELETE language that does not apply:]

If you take part in this study, the main difference between your regular care and the study is [describe.]

[Include if true] This study is not part of your health care.

***How is this research funded?*** [Include for sponsored research. Otherwise, delete.]

***[Usually sponsor name]*** is funding this research and is also called the sponsor. Sponsors may change during the study.

## What happens if I say yes, I want to be in this research?

 [Tell the subject what to expect using lay language and simple terms. You must organize and format the information in a manner that will facilitate understanding. Include the following items:

* A time-line description of the study procedure. If practical, prepare a table, flowchart, or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits;
* The drugs or biologics that the subject will receive;
* All investigational devices used in the study;
* All hospitalizations, outpatient visits, and telephone or written follow-up;
* The length and duration of visits and procedures;
* If the study requires blood collection, indicate the amount in “baking” style measures (e.g., teaspoons, tablespoons, or cups) and frequency;
* The people the subject will interact with;
* The location(s) of the research site and research procedures;
* List experimental procedures and therapies and identify them as experimental;
* How often the subject must undergo procedures;
* Differentiate the procedures done solely for research purposes from the procedures done for standard care;
* Whether the research will contact the subject for future research;
* If the study involves testing for reportable communicable diseases (e.g. HIV, Hepatitis), list the reportable tests and tell the subject that the study team will report positive results to the Health Department;
* Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);

[Include for a clinical trial that involves randomization. Otherwise, delete.] The treatment you get will be chosen by chance, like flipping a coin. You and your study doctor will not get to choose the study treatment you receive. You will have an [equal/one in three/etc.] chance of receiving treatment. [For double-blinded research, add.] Neither you nor the study doctor will know which treatment you are getting, but in emergencies, the study doctor can quickly find out your treatment. [For single blinded research, add.] You will not know which treatment you are getting.

Include if this research will collect biospecimens for DNA analysis, conduct DNA analysis on biological samples collected for another purpose, share/transfer samples for DNA analysis, or share data on DNA analysis

***Does this Study Involve Genetic or Genomic Research?***

This study also involves genetic/genomic testing (analysis).

Genetic testing refers to the study of single genes. Genomic testing refers to the study of all of a person’s genes (genome). Genes are made up of DNA (deoxyribonucleic acid). You inherit genes from your parents. The genes control how your body grows and changes and how your body reacts to certain things. For example, genes you inherited from your parents determined your eye and hair color.

Scientists can collect genes from blood, saliva, or other tissue samples. We will collect DNA from your (***blood/saliva/cheek, etc***.). This testing and research may help us learn why some people are more likely than others to have ***[describe the disease or condition****]*.

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 may make it more likely for you to have a health problem, but 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.

***[Choose this paragraph or the next]*** We will not include your name or other identifying information on the ***[blood/ tissue]*** that came from you. We will apply a random code to this sample. We will link the code to your identity, but we will keep the link in a separate place. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. If you want to remove your ***[blood/ tissue]*** from this study, contact the study doctor or study team and let them know. If the link to your identity has not been destroyed, we will find your sample and destroy it. We cannot remove the information we learned about your DNA.

***[Choose this paragraph or the one above]*** No one will know that the ***[blood/ tissue]*** sample came from you. Since we will not link your name or other identifying information to the ***[blood/ tissue]*** sample, you cannot change your mind after you agree. We will not be able to find your sample to remove it. It will be forever separated or “unlinked” from your identifying information to protect your privacy. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. We cannot destroy this information.

***[Include if applicable]*** We may share your ***[blood/ tissue]*** the information we learn about your DNA with other researchers so they can use it to learn more about ***[insert condition] [or other conditions.]*** But we will not include any information that directly identifies you.

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.

 [If this research involves genomic data sharing with NIH, insert] [Genomic Data Sharing Model Language](#GenomicDataSharing).

***[Delete this section if the research is not a clinical trial.]***

## What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for*:* [Describe any responsibilities of the subject.]

## What happens if I want to leave the study?

[Add the following for studies involving multiple visits and/or collection of information over a period of time:]

***[Only if there are any risks associated with stopping study procedures, add either:]***  If you decide to leave the study, contact the study team so the study doctor can work with you to create a safe plan for your withdrawal. ***[If applicable]*** We will ask you to come in for a final study visit to check your health.

***[Include if you will ask the subject to come in for one last visit to collect data:]*** If you decide to leave the study, contact the study team. We will ask you to come to the research site for one final visit.

 [Include for FDA-regulated research. Otherwise, you may delete.]If you leave the research, we will keep the information about you that we obtained or created. Tell the study team if you want us to destroy the blood and other tissue samples that we collected while you were in the study. If the blood and other samples are not linked to your identity, the study team cannot destroy them.

If you leave the research, we would like to keep checking on your health. We will ask if we can review your medical record and collect data about your medical care in the future. If you agree to allow us to keep collecting data after you stop being in the study, we will handle this new data the same as the other research data.

 ***[Note: The consent document cannot give the subject the option of having data removed. If a subject withdraws from the study, the investigator must not access the subject’s medical record or other confidential records without first obtaining the subject’s consent and authorization. The investigator may continue to use data that were collected before the withdrawal. If the subject agrees to allow the research to continue collecting data about them after withdrawal, you will need to submit a consent form addendum for the continued data collection.]***

***[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.*** ***If the subject agrees to allow the research to continue collecting data about them after withdrawal, you will need to submit a consent form addendum for the continued data collection.]***

[Delete the following section if not applicable.]

## Can anyone remove me from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

* Your health changes and staying on the study is no longer in your best interest;
* You do not follow the study rules or you no longer meet the requirements to be in the study; or
* The sponsor or the study doctor stop the study.
* ***[Add any other reasons the subject will be withdrawn.]***

*What are my other choices if I do not take part in this study?*

***[You must describe any alternative treatments that are available to the subject. Include “other research studies” and describe the UHealth standard of care, when applicable. If the subject can receive the study treatment outside the study (e.g. approved drugs), make this clear. Delete this section if the only alternative is not to participate.]***

You do not have to be in this research study to get care for your ***[disease/condition]***.If you decide not to take part in this study, you have other choices. For example:

***[Select relevant options from the list below, and add other available alternatives.]***

You may decide not to get treatment, but receive comfort care to help you stay as active and comfortable as possible.

You may choose to get the regular care described above for ***[disease/condition]***.

You may choose to take part in a different study if one is available.

The FDA approved the study treatment. You may receive ***[study treatment]*** outside of this study.

These options may have risks. Discuss the possible risks and benefits with your study doctor.

## Is there any way being in this study could be bad for me?

***[Delete this section if there are no risks or discomforts. Please note that there are usually risks or discomfort to a study, however minimal they might be. Please also consider risks to privacy and confidentiality. See the Appendix: Sample Risks below for examples.]***

There ***[are/may be]*** risks if you take part in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to this research. Inform the study team as soon as possible if you experience any pain or discomfort.

***[Consider using a table format to present the risks of procedures.]***

***[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. See attached Appendix for Risk Language for Inclusion. Modify as relevant.]***

* ***[Physical risks***
* ***Psychological risks***
* ***Privacy risks***
* ***Legal risks***
* ***Social risks***
* ***Economic risks]***

***[Include for research with an aim to assess the safety or when the PI/Sponsor does not know all of the risks, including all research involving an investigational product. Otherwise, delete.]***

In addition to these risks, this research may hurt you in ways that we do not yet know. These harms may be a minor inconvenience or may be so severe as to cause death.

[Include for studies involving non-sensitive data.] There is a risk that someone not involved in this study could access your information but we have procedures to protect your information.

[For studies that collect data with psychosocial risks, such as information on genetic predisposition to diseases, drug or alcohol abuse, illicit behaviors, etc.] There is a risk that someone not involved in this study could access your information. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, your employment, or make it harder to get insurance or a job. We have procedures in place to protect your information. [GeneticDataRepositories](#GeneticDataRepositories)

*What about Birth Control?*

Include the language below when the study could adversely affect an embryo, fetus or a breastfeeding baby, or if it is unknown whether such harm could occur. Check the protocol to see if there are specific requirements for contraception.

**Note: When the sponsor knows the study drug/device can harm an embryo or fetus, or if the sponsor does not yet know if the study drug or device could cause such harm, the IRB will usually require at least one of the methods included in the list below.**

**Contraception Requirements for Women**

[Include if applicable] Liquids in your body, such as the fluid in your vagina, could absorb some of the study drug. If you have sexual relations with a male, you can pass the drug on to your partner. To prevent exposing your partner to the drug, he must wear a condom during sexual relations.

The study drug(s)/device(s)/procedure(s) may harm an unborn or breastfeeding baby.

* If you are pregnant or breastfeeding, you cannot take part in this study.
* If you think you may be pregnant, you should not take part in this study.
* If you are able to become pregnant, we will perform a test to see if you are pregnant before you begin the study. ***[***If the study includes more than one pregnancy test, add: [and while you are in the study.]
* You must not get pregnant or breastfeed while you are in this study.

If you are a woman who can become pregnant, you must take measures to avoid becoming pregnant while you are in this study.

The following are acceptable measures to avoid becoming pregnant:

* Abstinence (not having sexual relations with a person of the opposite sex)
* A hormone implant under the skin
* A device in the uterus to prevent pregnancy (IUD)
* Sexual relations with a male partner who has had a vasectomy
* If you are female who has had surgery to prevent becoming pregnant such as a tubal ligation.
* Injections of hormones
* Birth control pills (contraceptives)
* GnRH Agonists (zoladex, triptorelin, leuprolide)-these agents are only effective if they have been in continuous use for at least 3 months [GnRH option only to be included if breast cancer subjects]

You must use birth control for at least [include the timeframe] before starting study treatment unless you abstain from sexual relations. You must use birth control during study treatment and for at least [include the timeframe]after stopping study treatment.

If you become pregnant while in this study, you must tell the study doctor as soon as possible (include if applicable) and you must stop taking the study treatment. The study doctor may want to follow your pregnancy and the health of your baby.

***[Include if applicable]*Contraception Requirements for Men**

[Include if applicable] Your body fluids, such as semen, may absorb the study drug. If this happens, you could pass the study drug to your partner during sex. You must wear a condom to prevent your partner from exposure to the study drug.

There may be risks to the unborn baby if your sexual partner is pregnant or becomes pregnant while you are in this study. If your partner is a woman who can have babies, you and your partner must either not have sex or use effective birth control while you are in this study. If you have not had a vasectomy, your partner should use one of the following forms of birth control:

* Abstinence (not having sex with a person of the opposite sex)
* A hormone implant under the skin such as Norplant
* A device in the uterus to prevent pregnancy (IUD)
* Surgery to prevent becoming pregnant such as a tubal ligation.
* Injections of hormones
* Birth control pills (contraceptives)

You or your partner must use birth control during study treatment and for at least [include the timeframe] after stopping study treatment. You should also refrain from donating semen during study treatment and for [include the timeframe] after stopping the treatment.

If your partner becomes pregnant or suspects becoming pregnant during study treatment or within [include the timeframe]after completing study treatment, you must tell the Study Doctor as soon as possible. Your Study Doctor may want to follow the pregnancy and may ask your partner to sign a consent form so they can collect information about the outcome of the pregnancy.

## What if new information becomes available?

## We will tell you if we have any new information that may affect your willingness to stay in the study.

## Will being in this study help me in any way?

 [Describe any tangible benefits to subjects. Avoid vague statements such as “you may or may not benefit.” State specifically if subjects are not expected to benefit directly. Note that Phase I clinical trials typically involve no expectation of direct benefit to subjects. Do not include monetary reimbursement, free clinic visits, or other incentives in this section. Place such language in its own section, such as “Will I Be Paid or Receive Anything for Participating?” The following are examples. Delete the examples that do not apply]

The study treatment may work better than the usual treatment, but we cannot promise any benefit. The study treatment might not work at all, or it might have bad side effects. Even if the study treatment does not help you, taking part in this study may help other people with similar conditions in the future.

 [Describe potential scientific/societal benefits].

Being in this study will not help you directly. However, your participation in the study may benefit other people in the future by helping us learn more about [describe the potential scientific/societal benefits].

[Include the following text if medical procedures or tests are being performed in the study solely for research purposes and will not be used for clinical care:] This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

[Include only for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

*Will being in this study cost me anything?*

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

The sponsor will provide the study drug free of charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

*[*Include for a clinical trial. Otherwise, delete.] You or your health insurance plan may have to pay for medical costs that are part of this study. 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 have to pay. You should discuss any questions you have about costs with the study doctor or study team.

***[For Category A device studies, include the following:]***

*[****The University of Miami****]* will bill your insurance company for the cost of the device.

The sponsor will provide [Describe types of activities covered by the study, e.g. lab tests, diagnostic tests, drugs, clinic visits] that are done for research purposes only and are not part of your regular care. [If subjects have to pay for any of the drugs or treatments required in the protocol, include information about the costs of those drugs and treatments.]

You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Health care providers will bill you or your health insurance for regular office visits (outside of the study) and standard treatment. You may continue in the research study after your release from prison. If you move out of the area, we will help you arrange care with a physician.

***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 taking part in this study. We will pay you by ***[a gift card, cash, check, etc.]*** at the end of the study. If you choose to leave or we take you off the study before you complete all of the study visits, you will receive [describe pro-rated payment].

We will pay you [dollar amount] for by ***[a gift card, cash, check, etc.]*** after [Visit 1, intervention x, each study visit, 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, we will pay you [describe pro-rated payment].

***If you will pay subjects different amounts for different visits/interventions, include a list of the visits/interventions and the payments.***

We may ask you for your social security number for payment purposes. We will not use it for any other purpose without your permission.

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

***[If using ClinCard, include.]***

Payment for participating in this study will be made using ClinCard. ClinCard is a MasterCard branded debit card that can be loaded with funds by the study team. We will [give/mail] you the card. You will also get information about how to use this card and whom to call if you have any questions. Money will be added to your card based on the study’s payment schedule (See consent compensation section). You may use this card online or at any store that accepts Mastercard.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth and will be overseen by the University of Miami study team. They will use this information only as part of the payment system for customer service reasons only. Your information will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study team for a replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

***[If applicable, include.]***

The sponsor and the University of Miami (UM) will use your information (data) and samples (blood, urine, etc.) for this study. They may keep, save, or dispose of the data they obtain from you or create about you. The UM or other researchers may use your data and samples for other studies after they remove all of the information that identifies you. They will not ask for your consent for this other research.

This study and other studies may result in products that can be sold. If this event happens, the sponsor or the UM may profit. They will not pay you or share any of the profits with you. Any blood, urine, tissue, or other biological specimens obtained from you for this study will become the exclusive property of the sponsor or the UM. ***[Or other institution, please specify.]***

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be compensated. Otherwise, delete.]Military personnel should check with their supervisor before accepting payment for participation in this research. We may ask you for your social security number for payment purposes. We will not use the number for any other purpose without your permission.

*What happens if I am injured or get sick because of this study?*

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

If you are hurt or get sick because 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 need to pay. Funds to compensate you for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain payment through the legal system

***[Sponsored studies that involve greater than minimal risks:]***

If you are hurt or get sick because you are in this study, treatment should be available. If you are hurt because of ***[choose: a study procedure that is done correctly or because you took the study drug as you were told, because of the device you received],*** the Sponsor will pay to treat the injury. The UM and the sponsor are not planning to pay for pain, lost wages, and other costs you incur because you were hurt. If you sign this document, you do not give up any of your legal rights to obtain payment for an injury through the legal system.

If the sponsor pays any of your medical expenses, we may require you to give the sponsor your name, date of birth, and Medicare ID or social security number.

***[Studies that involve minimal to no risks:]***

Although risks are unlikely, if you are injured, 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 need to pay. Funds to compensate you for pain, expenses, lost wages and other damages caused by the injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

***Does anyone on the study team have a related conflict of interest?***

***[If the PI, any member of the study team, and/or their spouses or dependent children have an outside interest or have intellectual property rights related to this project, or if you are aware of any institutional conflict of interest pertaining to this study, include the applicable statements below:***

*[****Study doctor****]* has disclosed that he/she has a personal interest related to this study.

The UM has an 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 about reviewing disclosures of financial interest or the conflict of interest management process at the UM, please call 305-243-0877.

## What happens to the information collected for the research?

We will do our best to protect your personal information (data). Data includes data from this research study and from your medical records. It will also include the results of any genetic analysis or genomic sequencing we conduct, if these procedures are part of this research. We have strict rules to protect your data.

We will limit access to people who have a need to review your data. We will also limit who has access to your name, address, phone number, and other data that can identify you. The study doctor and his/her collaborators will consider your data confidential to the extent permitted by laws and regulations.

We cannot promise complete confidentiality. Some groups may have to inspect and copy your data, such as the IRB and other UM representatives who are responsible for managing and overseeing the study.

 [Include any/all of the following three statements as appropriate, deleting those that do not apply.

Add in any other steps, which will be taken to protect the subject’s confidentiality.] We will remove identifiers from the data we collect about you. After we remove all of the identifiers, we will place a code on the data. We will link the code to your identity and keep the link in a location separate from your study data. We will keep your study data on encrypted computers. The data we send to the sponsor will not include information that identifies you.

We may publish and present what we learn from this study, but none of this information will identify you directly.

We may use the data and samples (blood, urine, tissue, etc.) we collect from you for other research in the future. We may also provide the data and samples to another researcher for research. We will remove information that can identify you if we use or share your data and samples for other research. After we remove the identifiers, we will not ask for your consent to use or share your data or samples for other research. .

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

* Members of the research team
* People in departments or on committees responsible for overseeing the research
* [Include if applicable:] People who do tasks for the study, such as scheduling tests, performing procedures, and dealing with billing.
* [For federally funded studies only, include the funding agency and:] The U.S. Office for Human Research Protections
* [For FDA-regulated studies only, include:] The U.S. Food and Drug Administration (FDA)
* Regulatory Authorities from other countries
* [Include if applicable:] The study sponsor
* Collaborating researchers outside of the UM, including researchers at [name collaborating institutions]
* Companies or groups performing services for the study, such as [add examples of services, e.g.: laboratories outside of the UM]
* [Include any other individual or entity who may access study records.]

Include if the study is testing for information about any special categories of information. Delete the categories of information that the study will not access. If the study will not access sensitive information, delete:

For this study, we must access and share data about you that is sensitive. We will share this sensitive data with the sponsor and the other individuals listed above may see the information in your research file. This data includes [Select the applicable categories of information: information about your HIV status, hepatitis B and/or C infections, sexually transmitted diseases, treatment you have received for mental health conditions, and treatment you have received for alcohol or other substance abuse.] If you test positive for some of the diseases listed above, the UM must report this result to the Florida Department of Health.

***If the study involves HIV testing:*** The study sponsor, FDA and Department of Health and Human Services (DHHS) may review your records and the results of your HIV test. UM employees or other agents may also review your records for audit purposes. However, laws will require them to keep your data confidential. Florida law requires the UM to report all positive HIV test results to the Florida Department of Health. The results we report must include information that identifies the patient. By signing this consent form, you are agreeing to this use, access and disclosure of your sensitive information.

You can obtain an HIV test without giving the testing site your identity. You can find testing sites in many places in Dade County.  You can visit the following site, to find these testing sites: [http://miamidade.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids-services/counseling-testing-sites.html](https://nam01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fmiamidade.floridahealth.gov%2Fprograms-and-services%2Finfectious-disease-services%2Fhiv-aids-services%2Fcounseling-testing-sites.html&data=02%7C01%7Ccmg345%40med.miami.edu%7Cf0d56a1bb9cc408bc7e608d7d71c9342%7C2a144b72f23942d48c0e6f0f17c48e33%7C0%7C0%7C637214390034243850&sdata=eTGDgURO44ol45zXbUt1Sa%2FtNtRT0cpGVnuIBKmlYF4%3D&reserved=0)

[Include if the study team will access the Electronic Medical Record and/or if the consent form or any test results will be added to the UHealth Medical Record.]

If you are, or have been, a patient at a UM facility, you will have a UM electronic medical record (EMR). We will add research data to your EMR so doctors taking care of you can use this information for your medical care. Your EMR will show that you are in a research study. We will also include a copy of this signed consent form in the EMR to show your doctors that you are in this research.

The data may describe the investigational products you received and anything else that may affect your medical care or place you at greater risk of harm. The intent is to give information to caregivers who provide your medical care while you are on this study.

UM doctors, nurses and other staff will have access to this data. These people are not part of the research team but are involved in providing your medical care, or they perform other tasks related to your medical care. Laws, such as HIPPA, will require them to keep your data confidential.

We suggest that you tell any non-UM doctors that you are in a research study and they can obtain more information if the request it.

The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

 [Include for a clinical trial. Otherwise, delete.] UHealth will grant direct access to your medical records to the sponsor, monitors, auditors, the IRB, and the FDA so they can conduct or oversee the research. By signing this document, you are agreeing to this access.

 [Include if a HIPAA authorization is required. Otherwise, delete.] Federal law provides more protections for your medical records and related health information. The second part of this consent form, the University of Miami HIPAA Authorization for Research, describes these safeguards.

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, we may need to give your records to people and agencies within the criminal justice system, when necessary, and allowed by law.

[Include if registration on clinicaltrials.gov is required. For assistance determining if registration on clinicaltrials.gov is required, use the [Applicable Clinical Trial (ACT)](https://nam01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fprsinfo.clinicaltrials.gov%2FACT_Checklist.pdf&data=02%7C01%7CARobledo%40med.miami.edu%7C5fb8fe2f2e8a46d9f82f08d725a181fc%7C2a144b72f23942d48c0e6f0f17c48e33%7C0%7C0%7C637019247921039284&sdata=3NAbd8Ul0E26jQ%2FzqkKxRrMKZN2bh%2BtgwDwTKfax8Go%3D&reserved=0) Checklist found on clinicaltrials.gov.]

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.

 ***[Certificate of Confidentiality: If the NIH is funding this research, you must include this language. If you have submitted or plan to submit an application for a Certificate of Confidentially, you must include this language.]*** A Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) covers the information obtained or created for this study. This CoC prevents the study doctor and study team from disclosing or using information, documents, or biospecimens that may identify you in lawsuits and criminal action. They cannot provide data in response to any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the court cannot use the data collected in this study as evidence in a proceeding unless you consent to this use. The study doctor and study team cannot share information, documents, or biospecimens protected by this CoC with anyone not connected with the research, except:

* To a federal agency sponsoring this research when they need data for auditing or program evaluations;
* To meet the requirements of the FDA;
* If a federal, state or local law requires disclosure such as a requirement to report a contagious disease;
* To report the information if you tell us that you want to seriously harm yourself or others;
* If you consent to allow us to share information for your medical treatment, to an insurer or employer to obtain information about you; or
* If an investigator uses the information or specimens for other scientific research, as allowed by federal regulations protecting research subjects.
* To the UM doctors, nurses and other 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 sharing information about yourself and 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 study team to release it.

If you consent to any disclosure for any other purpose, this CoC will not prevent the UM from disclosing it. If the UM shares information in response to your consent, the CoC may no longer protect the information.

***Will I receive any results from this research?***

Use this section to inform subjects whether they will receive any study results. Caution: if test results are experimental or come from a non-CLIA certified lab, CMS regulations prevent you from providing the results to subjects, even if the subject is not on Medicare.

Some tests done on your samples will be only for research and have no clear meaning. So, it will not affect your health care. Sometimes researchers perform tests are done on samples that are not linked to your identity. If the results of these tests may affect to your health and the study team is able to identify you, the researchers will attempt to contact you to let you know the results.

If study team gives your genetic tests results to you, it may be because they think you could have a health risk. They may advise you to have the test re-done by a certified lab to check the results. If this happens, then you may want to ask your own doctor if you should have the test redone. You may also want to get genetic counseling. The research will not pay for those extra services.

[***If the study will share data with NIH repositories, include language found*** HERE.](#Repository)

*Are there any optional parts of the study?*

[Include this section in the consent form if the research includes optional components, such as sample collection for correlative research, or banking of data or specimens for future unspecified research. Delete if there are no optional study components. Use the language below to introduce the optional activities, followed by specific information about the optional study component(s):

* Purpose of the optional study
* Procedures specific to the optional study (e.g. completing a questionnaire)
* Who will use information from the optional study, and how confidentiality will be protected
* How to withdraw from the optional study if the subject chooses to stop participating
* Include yes/no initial boxes for each optional study component. Clearly, state what yes and no mean for each optional study.]

This part of the consent form is about additional optional parts of the study that you can choose to take part in. Things to know about these other parts of the study:

* They are optional. You can still take part in the main study even if you say “no” to any or all of these parts of the study.
* These parts of the study will not help you directly. We hope the results from these other parts of the study will [describe the potential scientific/social benefits, e.g.: help other people with your disease in the future].
* [If applicable] We will not tell you the results of these parts of the study, and we will not put the results in your medical records.
* Taking part in these other parts of the study will not cost you anything. [If optional research requires additional time or additional study visits, explain any related costs that are not covered by the study, e.g.:] You will have to pay for basic expenses like any childcare, food, parking, or transportation needed for optional study visits.

Initial your choice of “yes” or “no” for each of the following optional parts of the study.

***Include the following information for each study:***

* ***Name of study (if applicable)***
* ***Study purpose***
* ***Description***
* ***The reason why subject might want to participate***
* ***The reason why subject might not want to participate***

*May we contact you by email?*

**[If the research team is planning to use email to communicate with study participants, please include this language.]**

We are requesting your email address so we can[describe how the study will use the email]. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. We will not send sensitive, detailed personal information by email. You should not send this type of information either. You also should not use email to convey information of an urgent nature. If you need to talk to someone immediately, please contact[Name, Title, and Phone Number for appropriate contact person, such as the lead investigator or physician on call]. You do not have to provide your email address to participate in this study. Please initial 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.

 [Include [***GDPR***](#GDPR) language if the data collected through this research are subject to the GDPR.]

PARTICIPANT’S STATEMENT/SIGNATURE

You will receive a signed and dated copy of this consent form if you agree to take part in this study and sign the form.

* *I have read this form and a member of the study team explained this research study to me.*
* *I had a chance to ask questions, and a research team member answered my questions. The research team told me whom to contact if I have more questions.*
* *I agree to be in the research study described above.*

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

Signature of Participant Date

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

Printed Name of Participant

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

Signature of Person Obtaining Consent Date

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

Printed Name of Person Obtaining Consent

***Remove “signature of participant” above if the subject is a child or is incapable of consenting.***

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

Signature of Parent(s)/ Individual Legally Authorized Date

to consent for the child to participate

Printed Name(s) of Parent(s)/ Individual Legally Authorized

to consent for the child to participate

***Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s participation in the research. Contact legal counsel if any questions arise.***

|  |
| --- |
| ***If the IRB determined that the permission requires the signature of both parents, but the signature of second parent was not obtained, indicate why: (select one)*** |
| * Second parent is deceased
* Second parent is unknown
* Second parent is incompetent
 | * Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***If the IRB approved inclusion of cognitively impaired adult participants who cannot personally consent, you must submit a proxy consent document.***

***Assent is usually required for participants who are minors age 7 to 17 years.***

I described this study to the child in a manner suited to the child’s age and ability to comprehend. I answered all of the child’s questions about this study. I asked the child questions to see if the child understood that the procedures are research and that s/he doesn’t have to participate if s/he doesn’t want to.

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

Signature of Person Obtaining Assent Date

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

Printed Name of Person Obtaining Assent

A witness is only required if:

1. The subject, parent or LAR is unable to read the consent document;
2. The subject, parent or LAR is unable to sign the document due to physical limitations; and/or
3. Consent is obtained using the short form process, and this consent document is the summary.

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

Signature of Witness Date

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

Printed Name of Witness

***Review the appendixes following this section. Include or delete them as applicable. When the document is complete, delete all text after the signature section, i.e. this line onward.***

**ADDENDUM 1: UNIVERSITY OF MIAMI**

 **RESEARCH AUTHORIZATION**

**What is the purpose of this part of the form?**

State and federal privacy laws protect the use and disclosure of your Protected Health Information “PHI”. Under these laws, your health care providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. We call these people and institutions “Providers” in this form.

**What Protected Health Information will be used or shared?**

You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

* Your past medical history,
* Medical information from your primary care physician,
* All other medical information relating to your participation in the study listed at the top of this document; and
* Genetic or genomic data obtained by analyzing the biological samples you provided, if the consent document describes genetic analysis.

**Who may receive my Protected Health Information?**

The Providers may use and share your health information with:

* The Principal Investigator and his/her research staff
* Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
* Groups that collaborate and sponsor research (Cooperative Groups)
* Institutional Review Boards (groups of people who oversee research)
* Other persons who watch over the safety, effectiveness, and conduct of research
* The Sponsor of the research, its agents, monitors, and contractors
* Other participating researchers; and
* Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of your but are not involved in this research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, we may include the study-related information in your permanent hospital, clinic, or physician’s office records.

**Why will my Protected Health Information be used and disclosed?**

* Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
* The research sponsor, its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in the first part of this document and for other activities related to the research. These activities include assessing the safety or effectiveness of the drug, device or treatment that we are studying, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
* The University of Miami’s clinical trial organizations will use your information to review and support clinical trials at the University.
* Other University of Miami offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance may use your information to ensure the study teams are performing the research correctly.
* U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who must use your information to review or oversee this research and to review the data so they can decide whether to approve a new drug, device or other health care product for marketing.

**What other information should I know?**

1. Once the study team has disclosed your information to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your r decision will not affect your right to other medical care.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at 1531 Brescia Avenue, Casa Bacardi, Coral Gables, Fl. 33146.
4. If you revoke this Authorization, you will not be able to continue taking part in the research.
5. While the research is in progress, you cannot access and read your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. A study team member will give to you a copy of this authorization after you sign it.

|  |  |
| --- | --- |
| *Signature of participant or participant’s legal representative**Printed name of participant* | Date |

**Addendum 2: Genetic/Genomic Sharing**

 *[Include the language below if genetic data may be shared, now or at some time in the future, with public data repositories under the* [*NIH Genomic Data Sharing (GDS) Policy*](https://kb.wisc.edu/hsirbs/77276)*. This includes:*

* ***NIH-funded studies***
* ***Studies likely to receive NIH funding in the future***
* ***Collaborative research with someone who has NIH funding***
* ***Studies that will voluntarily share data with public repositories***

***If none of the above apply, remove this part from the consent document.***

Your blood and tissue samples contain DNA. DNA incudes the genes that serve as the "instruction book" for the cells in our bodies. Your samples and health information will help us study how genes play a role in diseases such as cancer, heart disease, and diabetes.

Researchers will use (analyze) DNA from the samples you provided to study your entire genetic sequence, known as your “genome.” We will use your genomic data to find how the data differs and is the same among people who have a disease or other health trait.

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 may make it more likely for you to have a health problem, but 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.

Since the NIH is funding this study, we will need to share genetic and genomic data with an NIH federal repositories (databank). The NIH is a US research agency that is part of the US government.

If you agree, we will share your genomic data (not your samples) with a databank approved by the NIH. These databanks collect the results of many genetic and genomic studies and pool the data with information from other research participants. If you allow us to share your data, scientists will use it to better understand many diseases and develop better treatments. This research may help others like you in the future.

These central databanks will store your genetic and genomic data and give them to other researchers for different studies. These researchers must be approved to receive your data.

We will not share your name, birth date, or any other information that could directly identify you. We will remove this information and apply a code to the data and keep the link between the code and your identity.

Even so, there is a chance that people may combine your genomic data with other data and identify you or a group you belong to like an ethnic group or other people with the same disease. If your genomic information is linked back to you, someone might use this information to learn something about your health.

Your genomic data is unique to you, but you share some genomic data with your children, parents, brothers, sisters, and other blood relatives. So, it may be possible that genomic data from them could be used to help identify you. It is also possible that genomic data from you could be used to help identify them.

There also may be other privacy risks that we have not foreseen.

The NIH prohibits people from trying to identify people whose genomic information is in an NIH-designated repository.

To help us protect your privacy, we have obtained a legal document called a Certificate of Confidentiality (CoC). The CoC helps us to protect your data from most subpoenas or other legal demands. With your consent, your genomic and health data can still be shared for purposes you agree to, such as with other researchers for research purposes.

You do not have to allow us to share your genetic or genomic data. You can decide not to allow us to share your data and you can ask us to remove data you allowed us to share. Whatever you decide, you will not be penalized or lose any benefits. You can still join this study if you decide not to allow us to share your data.

We do not think that there will be further risks to your privacy and confidentiality when we share your genetic or genomic data with these banks. However, we cannot predict how genetic data will be used in the future. Scientists could use the genetic data to study a wide variety of diseases.

Initial below to indicate your decision to allow this research to share your genetic and genomic data as described above.

I agree \_\_\_\_\_\_\_\_\_ I disagree \_\_\_\_\_\_\_\_

Addendum 3: General Data Protection Regulation

***[Instructions: Use this part if the research obtains, collects or creates Personal Data[[1]](#footnote-2) from subjects located in the EU or EEA. If the research is obtaining “Sensitive Data[[2]](#footnote-3),” explicit consent is required. Delete all language in red type before submitting this Notice for review.] If this study does not require GDPR notice or consent, remove this part from the consent document.***

***Notification/Consent for Collection and Use of Study Data***

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.]*** to properly conduct this research. As we conduct research procedures with your study data, we may create new study.

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

***[Delete any categories of information that you will not collect or create.]***

* Contact Information
* Health information
* Your racial or ethnic origin
* Your political opinions
* Your religious or philosophical beliefs
* Your sexual orientation or beliefs
* Genetic Data
* Information about your response to the research procedures

***[Insert the categories of any additional data that you will collect.]***

***[Include, if applicable, otherwise delete.]*** 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. ***[Describe any other procedures that use an automated process to make decisions about the subject.]***

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: ***[Delete any category that is not applicable.]***

* 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

***[List the additional categories of individuals who may receive access to Personal Data and describe the reason for the disclosure.]***

***[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 are responsible for using your study data for this research. ***[Include the appropriate contact information depending on which campus the research is conducted:]*** The University of Miami Privacy Officer is Andrew Stoquert**.** You can contact Mr. Stoquert by phone at +1 (305) 243-7376 or by email at a.stoquert@med.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.

***Addendum 4 – Use this language when applicable***

**Can I receive a COVID-19 vaccine while I am in the study?**

The study drug has not been tested together with vaccines for COVID-19. It is not known if taking the vaccine before, while or after receiving the study drug(s) can cause any side effects or how the study drug(s) may impact the effectiveness of the vaccine. If you have received or are planning to receive the vaccine, please inform the study doctor. Your study doctor will talk to you about the possible risks of receiving the vaccine at the same time as the study drug(s). Your study doctor will also explain if receiving the vaccine will affect whether you are eligible for the study.

Since this is the first time anyone will be given the study drug, it is important to understand whether the drug causes side effects by itself. Since the vaccine could cause side effects while you are receiving the study drug, it is recommended that you consider one of the following options:

* + Getting all doses of the vaccine at least one week prior to receiving the first dose of study drug
	+ Waiting at least 6 weeks after receiving the first dose of the study drug before getting the vaccine

The decision to receive a COVID-19 vaccine and when to receive it is yours to make. If you do choose to be vaccinated, please keep a record of the name of the vaccine you receive, the date(s) you receive it, the batch number and any side effects that you had. Make sure you provide this information to your study doctor.

If you have any questions or concerns, please speak with the study doctor. As always, your participation in this study is voluntary.

***Addendum 5 - Sample Risk Language – this section is a reference so you can add common risk language. Remove this part from the consent document before submitting it to the IRB.***

**Risks associated with stopping your current drugs (washout period):** During this study the drugs you normally use for your condition will/may be stopped for up to *[# days/weeks/months]*. You will/may receive no medication or receive medication at a dose that may not help your condition. As a result, you will/may have an increase in symptoms including *[description]*.

**Allergic reaction:** As with any drug, there is a chance you could have an allergic reaction to *[drug]*. Signs of an allergic reaction include: itching, skin rash, sudden drop in blood pressure, loss of consciousness with or without seizures. An allergic reaction could be life threatening. Seek medical help immediately.

**Biopsy:** 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.

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.
* Complications from biopsies including bleeding or infection could lead to:
	+ the need for further treatment,
	+ blood transfusions, or
	+ hospitalization with extra procedures

Local anesthetic injection for biopsy can cause allergic reactions that may be mild or may be serious and life threatening.

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.

**Blood draw risks:** Drawing blood may cause brief pain from the needle stick, bruising or swelling at the site. Rarely, people faint during a blood draw or develop an infection.

**Bone marrow aspirate:** The risks of a collecting bone marrow include pain, a bruise at the site of puncture, fainting. Rarely, people develop an infection or a small clot or swelling in the area of the puncture.

**Catheter:** Part of this study involves inserting a thin hollow tube, called a catheter, into one of your ***[vein/artery]*** blood vessels. There may be slight discomfort while the study team inserts the catheter. Occasionally, a bruise or small lump may form at the site. A small amount of bleeding may occur around the catheter site. Rarely, a local infection may occur around the catheter site. *[Include the following for arterial cauterization]* Very rarely, an arterial catheter may cause reduced blood flow. If this event happens, you will need urgent surgery to re-open the artery. Usually, this type of event occurs only when the catheter remains in the artery for long periods.

**CT (Computed Tomography) scan risks:** If you take part in this study, you will have one or more medical imaging studies that uses radiation. One type of imaging study that involves radiation is a whole body CT scan. 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. To give you an idea about how much radiation you will get, we will compare the radiation you will receive from the CT scan with an every-day situation. This research gives your body the equivalent of about 3 extra years' worth of the natural radiation you normally receive. The radiation dose we have discussed is what you will receive from the CT scan and does not include any other 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 to the dye. This reaction may cause symptoms ranging from mild itching, or a rash, to severe difficulty breathing, shock, or rarely, death. The dye 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 you have before the procedure. If you have any of these problems, you may not be allowed to have a CT scan *[or continue in the study.]*

**Drowsiness:** Because the study drug may make you sleepy, you should not operate heavy equipment or drive a car when taking the study drug if your study doctor tells you not to.

**Electrocardiogram (ECG):** This is a painless test that records the heart’s electrical activity. The test involves attaching soft, sticky patches to the skin of your chest, arms and legs. After you complete this test, we will remove the sticky patches. You may have some skin irritation at the site of patch removal, but this irritation typically goes away on its own

**Exercise testing risks:** The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.

**Fluorescein Angiography:** This procedure injects a fluorescent dye into the bloodstream to highlight the blood vessels in the back of the eye to photograph them. Adverse reactions to the dye are uncommon but may include the following: nausea, headache, upset stomach, vomiting, light-headedness, fainting, hives, or leakage of dye out of the blood vessel. Very rarely, 1 in 220,000, a sudden life-threatening allergic reaction can occur. Such sudden but rare reactions include breathing difficulties, shock, convulsions, or the abrupt loss of heart function. These conditions require emergency medical treatment.

**Hypoglycemia:** This medication could lower your blood sugar too much (hypoglycemia). Hypoglycemia can make you feel tired, dizzy, sweaty, and/or nauseated. Also, it could cause your heart to feel as if it is racing. There may also be other effects. Untreated hypoglycemia could cause convulsions, loss of consciousness, and can lead to death.

**Clinical MRI (Magnetic Resonance Imaging) risks:** 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 in your body.

MRI scanning is painless, but you might experience discomfort in the machine. You will hear loud beeping. Hammering noises occur during the study. You may also feel claustrophobic when you are inside the MRI, or after lying in one position for a long time. You might also experience stimulation of your body's nerves, which feels like a gentle tap or sensation of mild electric shock. *[If appropriate, also discuss the risks of sedation here.]*

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:** You will receive gadolinium through a vein in your arm for the MRI. Gadolinium 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. Treatment is available if these problems occur.

**Nephrogenic Systemic Fibrosis Risk Associated with Gadolinium:** Some people who have had MRIs with a gadolinium-based contrast agent 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 the skin and the liver, lungs, muscles, and heart. That event has usually occurred only in people who are middle-aged and have 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 the brain, spinal cord and nerve tissue and bones. This deposit appears to collect over a person’s lifetime and does not seem to cause renal (kidney) or hepatobiliary (liver and gallbladder) problems. Neuronal and bone tissue deposits seem to happen to all patients exposed to gadolinium. Scientists have found it in people who have received only four doses of gadolinium. We do not understand the importance of these findings. Scientists have not seen any long-term effects, but they may find them in the future.

**MUGA (Multiple Gated Acquisition) scan:**  A MUGA scan is a noninvasive diagnostic test used to evaluate the pumping function of the ventricles (lower chambers of the heart). During the test, a small amount of radioactive tracer is injected into a vein. 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. The MUGA scan gives your body the equivalent of about two extra years' worth of this natural radiation.

**PET (Positron Emission Tomography) scan risks:** A positron emission tomography (PET) scan is an imaging test that allows your doctor to check for diseases in your body. The scan uses a special dye containing radioactive tracers. You may swallow the tracers or the study team may inject them into a vein. The PET scan will expose you to radiation. 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. The PET scan gives your body the equivalent of about 6 extra years' worth of this natural radiation. This radiation is in addition to the radiation you receive from other tests and the unavoidable radiation you receive from the environment.

**Placebo risks:** During this study there is a *[#]*chance that you will receive a placebo. A placebo looks like the study drug, but it includes no active ingredients. Taking a placebo could lengthen the amount of time before you receive a treatment that may work. During this time, you may experience worsening of your condition, including increased symptoms such as: *[symptoms]*. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.

**Psychological risks:** Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

***[SOC]* Radiation Exposure Risks:** Since the radiation procedures used in this study are all standard of care (SOC), the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, participating in this study will not expose you to additional radiation. .

***[Non-SOC]* Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and human-made sources. We have compared the estimated radiation dose that you will receive as a participant in this type of research to the limits allowed for a radiation worker. This limit is low, and we do not expect it to harm you. If you take part in this study, the amount of radiation you receive will be [***below/\_\_\_\_\_times above the limit]*** allowed for a radiation worker. The person obtaining your consent can answer any questions you have. We can provide detailed written information about the amount of radiation resulting from this study.

**Unknown Risks:** The experimental drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might affect your willingness to stay in this study.

1. ***Article 4 of the GDPR states “'personal data' means any information relating to an identified or identifiable natural person ('data subject')”***  [↑](#footnote-ref-2)
2. ***Per Article 9 of the GDPR, processing Personal Data about racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation is prohibited unless additional requirements are met such as informed consent from the data subject.***  [↑](#footnote-ref-3)