**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>*

*[Include the following if the consent is to be used by parents consenting on behalf of their child.]* A person who takes part in a research study is called a research or study subject. In this consent form “you” always refers to the research subject. 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

***[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.]***

You are asked to participate in 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]***.

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 **\_\_\_\_.**  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 \_\_\_\_visits and will last about ***[expected duration in hours, days, months, years]***. We expect about **\_\_\_\_**people at the University of Miami will join and about ***[number]*** people ***[around the U.S./worldwide]*** to participate in this research. If you are a student, your decision not to participate or to withdraw from the study will not affect your grades or other academic standings at the University of Miami. If you are an employee of the University of Miami, your decision not to participate or to withdraw from the study will not affect your employment at the University of Miami.

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.)]***.

Participation 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 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.

***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.]

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:

* 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 don’t 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 plus [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.]

This research is being funded by ***[sponsor name]*** also called the sponsor. Sponsors may change or be added.

## 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. This information must be organized and format in a manner that will facilitate understanding. Whenever appropriate include the following items:

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart 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 will be given to the subject;
* All devices that will be used;
* All hospitalizations, outpatient visits, and telephone or written follow-up;
* The length and duration of visits and procedures;
* If blood will be drawn, indicate the amount in “baking” style measures (e.g., teaspoons, tablespoons, or cups) and frequency;
* With whom will the subject interact;
* Where the research will be done;
* When the research will be done;
* List experimental procedures and therapies and identify them as experimental;
* How often procedures will be performed;
* What is being performed as part of the research study;
* What is being performed as part of standard care;
* What procedures are part of regular medical care that will be done, even if the subject does not take part in the research;
* 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);
* When applicable, indicate that the subject will be contacted for future research. ]
* ***If testing of reportable communicable diseases will be conducted, list the reportable test results under Florida Law.***
* ***If whole genome sequencing will be performed, include the language found***[*HERE.*](#Genomic)

[Include for a clinical trial that involves randomization. Otherwise delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you, nor the study doctor will choose what study treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each 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 be told which treatment you are getting, however your study doctor will know.

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

Include if applicable

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

This study also involves genetic/genomic testing. Genes control how your body grows and changes, and how your body reacts to certain things.  A genome is an organism's complete set of [DNA](https://en.wikipedia.org/wiki/DNA), including all of its genes. 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.

***[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:]

***[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 for FDA-regulated research. Otherwise, you may delete.]If you leave the research, we will keep the information about you and the samples (blood, urine, saliva, or other samples) we obtained from you.

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, this new data will be handled 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.]***

***[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.]***

[Delete the following section if not applicable.]

## Can I be removed 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?*

***[Describe any alternative treatment choices that the subject has outside of participation. If study treatment uses therapies available 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.

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 almost always 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 risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. Inform the study team as soon as possible if you experience pain or discomfort.

***[The risks of procedures may be presented in a table form.]***

***[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 that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.]***

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for studies involving only non-sensitive data.] There is a risk that your information could become known to someone not involved in this study.

[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 your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

*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 study drug/device is known to harm an embryo or fetus, or if it is unknown whether 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] The study drug may be absorbed into bodily secretions such as vaginal fluids and then passed on to your partner during sex.  Your male sexual partner must wear a condom to avoid being exposed to the study drug.

The study drug(s)/device(s)/procedure(s) may harm a fetus or a 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 volunteer for this study.

If you are able to become pregnant, you must have a pregnancy test before you begin the study. ***[***if tests are repeated, 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)
* Implantable hormone (e.g. Norplant)
* Intrauterine Device (IUD)
* Male partner has had a vasectomy
* Female sterilization
* Hormonal injection
* Oral contraceptives
* GnRH Agonists (zoladex, triptorelin, leuprolide)-these agents are only effective if they have been in continuous use for at least 3 months

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

**Contraception Requirements for Men**

[Include if applicable] Study drug may be absorbed into bodily secretions such as semen and then passed on to your partner during sex.  You must wear a condom to avoid being exposed to the study drug.

There may be risks to the embryo/fetus if your sexual partner is pregnant or becomes pregnant while you are in this study. If your partner is a woman of child bearing potential, you and your partner must either practice total abstinence or use effective contraception while participating in this study. One of the following forms of contraception should be used by you or your partner:

* Abstinence (not having sexual relations with a person of the opposite sex)
* Implantable hormone (e.g. Norplant)
* Intrauterine Device (IUD)
* Vasectomy
* Female sterilization
* Hormonal injection
* Oral contraceptives

You must use contraception during study treatment and for at least [include the timeframe] after stopping study treatment. You should also refrain from donating semen during therapy and for [include the timeframe] after stopping the therapy.

There is theoretical concern that study treatment can result in sperm abnormalities and/or can transmit harmful substances in their semen during sex. Therefore, if you are a male, you must remain abstinent or use a condom, even if you have undergone a vasectomy.

If your partner becomes pregnant or suspects becoming pregnant during study treatment or within [include the timeframe]after completing study treatment, you must inform the Study Doctor immediately. 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:]

Being in this study may [specify how the subject may benefit, such as: relieve your symptoms, help you feel better]. The study treatment may work better than the standard of care for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about [describe potential scientific/societal benefits].

Being in this study will not help you directly. But 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/will be have to pay for medical costs associated with taking part in 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 B device studies, include the following:]***

You or your insurance company will be billed only what the University will pay to obtain the device from the manufacturer.

There will be no cost to you for the [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. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by 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 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.

[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. You may be asked for your social security number for payment purposes. It will not be used 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 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 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 due to being in this study, treatment will usually be available. If you are hurt because of **[Chose one:** a correctly performed study procedure or because you took the study drug as you were told, **OR** because of the device you received**]** the Sponsor will pay for the cost of treating the injury. The University of Miami and the sponsor are not planning to pay for pain, lost wages, and other costs you incur because you were hurt. You do not give up any of your legal rights to obtain payment for an injury if you sign this consent document. [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.

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

Although risks are unlikely, if injury should occur, treatment will in most cases be available. 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.

***What conflict of interest issues may be related to this research?***

***[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 University of Miami 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 regarding disclosure review and the conflict management process at the University of Miami, please call 305-243-0877.]***

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

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. Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

If the results of the trial are published, the subject’s identity will remain confidential.

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.

Add in any other steps which will be taken to protect the subject’s confidentiality.] 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. ***AND/OR*** 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. ***AND/OR*** 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.

We may use the data and samples we collect from you for future research studies. We may also provide the data and samples to another researcher for future research. We will remove information that can identify you if we use or share the data and samples for future research. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your data or specimens for future research.

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
* [Include if applicable:] Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
* [For federally funded studies only, include the funding agency and:] 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 University of Miami, including researchers at [name collaborating institutions]
* Companies or groups performing services for the research team, such as [add examples of services, e.g.: laboratories outside of the University of Miami]
* [Include any other individual or entity who may access study records.]

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

Include if the study is testing for information about any of the following special categories of information will be created, accessed or shared. Delete the categories of information that will not be accessed. If no sensitive information will be accessed, delete:

For this study, we must access and share information about you that is sensitive. This sensitive information will be disclosed to the sponsor and the other individuals listed above may see the information in your research file. This information 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 the study involves HIV testing:* The investigator and his/her collaborators will consider your records confidential as permitted by law. The study sponsor, Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) may review your records and the results of your HIV test. Authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality may also review your records for audit purposes. By law, we must report all positive HIV test results to the Florida Department of Health with information identifying you if you test positive.

Anonymous testing for the HIV virus is available at other locations throughout Dade County.  You can visit the following site, which lists the confidential and anonymous 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)”

If we test you for HIV, hepatitis and some sexually transmitted diseases, we will need to report positive results to the health department. By signing this consent document, you are agreeing to this use, access and disclosure of your sensitive information.

[Include if UChart will be accessed for study and/or research information will be added to University of Miami 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.

[Include for a clinical trial. Otherwise delete.] 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.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These protections are described in the second part of this document, University of Miami HIPAA Authorization for Research.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted 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 this research is funded by the NIH, 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.]*** 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;
* 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.

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

Use this section to inform subjects whether they will receive any study results. Caution: if results of testing are experimental or are not performed at a CLIA certified lab, you cannot provide results to subjects.

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

If genetic tests results are given 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.

*Will information or leftover specimens be used for other research?*

Information collected about you and biospecimens collected from you will be used for this research and may also be used for other research studies here at the University of Miami. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

[***If information or specimens will be shared with data/specimen 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 optional 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 optional parts of the study will [describe the potential scientific/social benefits, e.g.: help other people with your disease in the future].
* We will not tell you the results of these optional parts of the study, and we will not put the results in your medical records.
* Taking part in the optional 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 e-mail?*

**[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 email will be used in the study]. 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[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

* *I have read this form and the research study has been explained to me.*
* *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
* *I agree to be in the research study described above.*
* *I will receive a copy of this consent form after I sign it.*

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

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)/Legally Authorized Representative Date

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

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

***Remove “Parent(s)” above if the subject is not a child or has an LAR other than the parent***

***If the IRB approved inclusion of cognitively impaired adult participants who cannot personally consent, you must obtain assent from that participant is s/he is capable.***

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

Signature of Adult Participant who is capable of Assent Date

***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.***

**PART 2: UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS**

**HIPAA AUTHORIZATION FOR RESEARCH**

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

State and federal privacy laws protect the use and release of your protected health information. Under these laws, your health care providers generally cannot release 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, Jackson Health Systems, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. These people and institutions are called “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

**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, any study-related information may be placed 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 and its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in this informed consent document and for other activities related to the research, such as assessing the safety or effectiveness of the drug, device or treatment being studied, 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 research is performed 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 are authorized by law may use your information to review or oversee this research or to see if a new drug, device or other health care product should be approved for marketing.

**What other information should I know?**

1. Once your information has been disclosed 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 right to other medical treatment will not be affected.
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 1400 NW 10th AVE, Suite 1200A, Miami FL 33136.
4. If you revoke this Authorization, you will not be able to continue taking part in the research. Also, even if you revoke this authorization, the institutions and people listed above will continue to use and disclose the information they have already collected if the information is needed to protect the reliability of the research.
5. While the research is in progress, you will not be allowed to see 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. You will be given a copy of this authorization after you sign it.

|  |  |
| --- | --- |
| *Signature of participant or participant’s legal representative*  *Printed name of participant* | Date  Printed name of legal representative (if applicable)  Representative’s relationship to the participant |

**Part 3. 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***

***Model Language:]***

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

At some point in the future, we ***[are/may be]*** required to share genetic data with federal repositories. Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government. The NIH and other central repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual’s genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body.

These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at UM. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

Part 4: 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.]*** 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:

***[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 is responsible for the use of 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 Helenemarie Blake-Leger**, Esq.** You can contact Ms. Blake by phone at +1 (305) 2435000 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.

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

**Allergic reaction:** As with any drug, it is possible that you could experience an allergic reaction to *[drug]*. Such allergic reactions include: itching, skin rash, sudden drop in blood pressure, loss of consciousness and/or associated with seizures, including the possibility of death.

**Blood draw risks:** Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.

**Bone marrow aspirate:** The risks of a bone marrow aspirate include the following: temporary discomfort and/or bruise at the site of puncture, fainting, and rarely, infection or a small clot or swelling in the area of the puncture.

**Catheter:** Part of this study involves having a catheter (thin tube) inserted into one of your blood vessels. There may be slight discomfort during the inserting of the catheters into the vein or artery. Occasionally, a bruise or small lump may form at the point of insertion of the catheter. 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 catherization]* Very rarely, an arterial catheter may cause reduced circulation requiring immediate surgery to re-open the artery. This complication is usually seen only when the catheter remains in the artery for long periods.

**CT (Computed Tomography) scan risks:** 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. 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 *[or continue in the study.]*

**Drowsiness:** Because the study medication may produce drowsiness in some patients, you should not operate heavy machinery, including driving a car as instructed by your doctor.

**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 the test is done and the sticky patches are removed, you may have some skin irritation in the location where the patches were placed, but this 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 in order 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). This could 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 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. *[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:** 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.

**MUGA (Multiple Gated Acquisition) scan:** 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. 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.

**PET (Positron Emission Tomography) scan risks:** 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. 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.

**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. This 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, you will not be exposed to any additional radiation for participation in this study.

***[Non-SOC]* Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of research has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and 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 make you change your mind about participating in the 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)