**Study Title for Participants:** [Insert Lay Study Title Here]

**Official Study Title for Internet Search on** [**http://www.ClinicalTrials.gov**](http://www.ClinicalTrials.gov): *[Insert Study Number (if applicable), Insert Official Study Title, Insert NCT (if applicable)]*

**Sponsor:** Name

**Protocol No:**

**Investigator:** Name

 Address

**Daytime Phone Number:** Phone Number

**24-hour Phone Number:** Phone Number [If more than minimal risk study]

**IRB Phone Number:** Phone Number

**Office of Clinical Research:** 813-877-2673 *[TGH CORE telephone number]*

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

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 signing this form on someone else’s behalf as their a legally authorized representative, please remember that “you” means the person participating in the study.

You should not join this research study until all of your questions are answered.

*[The below is intended to capture general information about the research study per the 2019 Common Rule changes.]*

Things to know before deciding to take part in a research study: *[remove any that do not apply]*

* The main goal of a research study is to learn things to help patients in the future. You are being asked to participate in this research study because [*briefly describe why the subject is being approached for this research-study*].
* The main goal of regular medical care, sometimes referred to as routine medical care is to help each patient. Routine medical care describes the care you will receive if you do not participate in this study.
* The purpose of this study to *[briefly describe the purpose of the study based on the primary and secondary objectives being evaluated]*. Other part of this study involves the use of an experimental (investigational) *[drugs, devices, or procedures]*, that are being tested for your *[state diagnosis from bullet point 1]*. An investigational *[drug, device, vaccine]* is one that has not been approved by the U.S. Food & Drug Administration (FDA). The *[drug, device, vaccine]* in this study is being used in a way that has not been approved by the U.S. Food & Drug Administration (FDA). *[Include a statement that this is a first in human study, if applicable]*
* If you choose to participate, you will be in the study for *[include expected study duration]*. During this time, *[include general information on study procedures and any other study specific information that can be briefly described. Allow for the remainder of the informed consent form to provide further clarifications/details]*.
* We do not know if you will receive any benefit from your participation. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you. *[Include any alternatives that the subject might undergo if he/she does not participate.]*
* The *[drug/device/procedure]* used in the study has risks. The most common and most serious are: *[List common and most serious side effects. Most common events occur > 20% or people, serious events are those believed to have caused hospitalizations, deaths, or other significant long-term disability]*.
* You *[will/will not]* be compensated for your participation. *[If there is compensation]* You will receive *[include total dollar amount]* if you complete the entire study.
* Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
* *[If applicable:* There is no cost to participate]. Your medical insurance may be billed for any routine medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like *[insert applicable general condition, as appropriate]*. You are being asked to participate in this research study because you have *[insert specific condition]*.

# **Why is this research study being done?**

This study is being done to answer the following question(s):

* *[insert relevant research question being answered by the research study]*. *If this is a first in human study, include a statement here.*

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your *[insert condition, diagnosis, early detection, other]*. The usual approach is defined as the care most people get for *[insert condition]*. *Delete this section if there is no intervention.*

# **What is the usual approach to my** [injury, disease, condition, cancer]**?**

*Use whichever statement is applicable:*

You do not have to participate in this research study. *This statement is sufficient if there are no alternatives for the participant.*

Alternatives to participating in the study include: *If there are alternatives, describe the procedures/treatments/interventions that the participant could receive such as taking a different course of treatment, etc.* Your doctor will explain the alternative treatments and which treatment may be best for you if you decide not to participate in this study.

There will be about *[insert total number of participants across all sites]* people taking part in this study. About *[insert total number of participants at local site]* people will take part in this study at Tampa General Hospital. *[If applicable, include the number of people that will take place at other sites in the US and outside of the US]* About [insert number] people will take part in this study at *[insert study site name]*.

# **What are my choices if I decide not to take part in this study?**

If you decide not to take part in this study, you have other choices. For example:

* You may choose to have the usual approach described above.
* You may choose to take part in a different research study, if one is available.
* *[If applicable]* You may choose not to be treated for your condition.
* *[If applicable]* You may choose to only get comfort care to help relieve your symptoms and not get treated.

# **What are the study groups?**

*Provide a brief, phase-specific description of the study groups.*

*For studies with multiple groups, indicate how many participants will be in each group, if known.*

*[For non-randomized trials]*If you are eligible for the research study, there will be *[insert number]* study group*(s)*; every participant will receive *[insert drug name or applicable therapy]***.**

*[For randomized trials]*If you are eligible for the research study, you will be randomly placed into one of*[insert total number of groups]* group(s)**.**  We will use a computer to assign you to one of the study groups. This process is called “randomization”. It means that you or your doctor will not choose which study group you are in. You will be put into a group by chance. You will have *[insert appropriate probability]* chance of being in Group 1 or Group 2 *[insert appropriate description of groups]*.

*[For blinded studies]* You and your study doctor *[will or will not]* know which group you will be randomly placed into.

*[If applicable]* You can only be part of one group.

*[For non-interventional studies]* There is no study groups in this research study.

# **How long will I be in the study?**

You will be in this research study for *[indicate total time in study]*.

*You may choose to include study specific language regarding different phases of the study (ex. time in screening, time on treatment, time in follow-up).*

The study doctor may stop you from taking part in this study at any time if he/she thinks it is in your best interest, or if you do not follow the study rules.

Your study doctor or *[sponsor name]*, the company who makes this drug, may decide to stop this study at any time without your consent. Your study doctor will tell you if this happens and will talk to you about other treatment options.

# **What exams, tests, and procedures are involved in this study?**

*[Any language included below MUST match the cost section. Explain what will be expected of participants throughout the entirety of the study]*

You will need to have the following extra tests to find out if you can be in the study:

* *List out all assessments being performed for the purposes of this research study. Define when, how, and where they may be performed as appropriate.*
* *If assessments are required for early discontinuation, include here.*

If you are eligible for the study, the following extra *[tests, procedures, assessments, other]* will be performed during the *[insert phase name]* and are not considered part of your routine care:

* *List out all extra assessments being performed for the purposes of this research study. Define when, how, and where they may be performed as appropriate.*

*[If the study involves storage of blood/tissue for future research]*

We are also asking you to allow us to obtain and store samples of your *[blood/tissue]* for use in future research. These samples may be used for research on your disease or condition and others to assist in the development of new treatments. We will take some of your *[blood/tissue]* in addition to that which has already been obtained for research purposes. *[If extra blood or tissue is being taken, explain how much extra will be taken and how this will impact the procedures for obtaining the samples. Be sure to include any additional risks the collection of blood or tissue will have on the research subject.]*

In addition to your sample being used for this study and future research, we would like to share it with other researchers. We will code your sample so that the researcher who uses it for other purposes does not know your identity. We will not release the code that links your sample to your personal identifying information for any reason.

*[If your study involves genetic testing, include the following text]*

This study also involves genetic testing. Genes control how your body grows and changes, and how your body reacts to certain things. Genes are what we get from our parents that help make our bodies what they are. For example, eye and hair color depend on the genes we received from our parents. 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 *[name 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.

Your sample *[will/will not]* be stored with personal information linked to it. We will not share any information that identifies you unless it is required by law. Because your genetic sample is linked to identifying information, please contact the study team if you decide to withdraw your consent to use your genetic sample at a later date. Once you withdraw your consent. the study team will remove your sample from the research and immediately destroy it so that it can no longer be used. Please understand that part of your sample may have been used before the withdrawal of your consent.

*[****OR*** *If the genetic sample is not linked, add the following language]*

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.

*[If your study involves whole genome testing, you must include the following text]*

As part of the genetic study, a sample of your DNA may have Genome Wide Association Studies (GWAS) performed. This analysis creates a very detailed picture of your DNA for researchers. In addition, information regarding your DNA and clinical information about you will be sent to the National Institute for Health’s Genome Wide Association Study (GWAS) data repository, where it will undergo genome-wide analysis and be shared with other investigators for research purposes. DNA and information sent to the GWAS will help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease, and may lead to better methods to select the best treatment options. Before your information is sent to the GWAS data repository it will be de-identified, which means that we will remove any identifying information such as your name, date of birth, address, etc. Thus, researchers using your DNA and clinical data will not be able to link this information back to you.

*[If the study is a pedigree study, add the following language]*

Generally, the sponsor does not provide genetic information about you to your family members. However, certain studies, called “pedigree studies” share genetic information among family members. The tests to be conducted on your blood/tissue sample will impact other members of your family. If you are willing to share your genetic information with your family you should sign this consent form. If this information is not something that you want shared with other family members, do not sign this informed consent form.

# **What risks can I expect from taking part in this study?**

*[For intervention studies:]* If you choose to take part in this study, there is a risk that the *[insert study intervention]* may not be as good as the usual approach for your *[injury, disease, condition, cancer]*.

*[For mandatory genetic testing:]*There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

*[If applicable]* You may lose time at work or home and spend more time in the hospital or doctor’s office than usual.

*[If applicable]* You may be asked sensitive or private questions which you normally do not discuss.

There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

There is also a risk that you could have side effects from the *[insert study intervention].*  These side effects may be worse and may be different than you would get with the usual approach for *[injury, disease, condition, cancer]*.

There may be side effects that are not known at this time. It is important to let the study doctor know if you notice or feel anything different. The study doctor may be able to treat some side effects. He/She can also decide to adjust your *[insert study intervention]* in an attempt to minimize side effects.

*[If there is more than one study intervention, each intervention should be listed separately]* Some of the side effects of *[insert study intervention]* that the study doctors know about are:

*[For device studies, if side effect percentages are not known, list side effects as one list without headers]*

## **Most Common**

* *[Insert most common side effects here, as a general rule these are side effects that occur in > 20% of patients]*

## **Less Common**

* *[Insert most common side effects here, as a general rule these are side effects that occur in 4-20% of patients]*

## **Rare**

* *[Insert most common side effects here, as a general rule these are side effects that occur in <4% of patients]*

*[For studies with imaging risks]* The *[insert type of scan]* that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation”. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The *[insert type of scan]*that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as *[insert estimate, ex 2 years’ worth]*of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

## **Reproductive Risks:**

*[If applicable, include any risks relative to pregnancy for both men and women. Specific contraception language should be added for female and male patients, as appropriate. For example:]*

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

Men who are in this research study should not get a sexual partner pregnant while taking the study drug *[If applicable also add the following:]* and for *[specify amount of time]* after the last dose of study drug. The effect of the study drug on sperm is not known.

*[Insert the following for research studies involving genetic testing]*

## **Genetic Information Nondiscrimination Act (GINA)**

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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

*[Use the mandatory statement below if conducting an online survey:]*

If completing an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

**What are my responsibilities in this study?**

If you choose to take part in this study you will need to:

* Keep your study appointments.
* Tell your doctor about:
	+ all medications and supplements you are taking
	+ any side effects
	+ any doctors’ visits or hospital stays outside of this study
	+ if you have been or are currently in another research study.
* *[Include as appropriate]* Write down in your medication diary when you take the study drug at home.

# **Will I benefit from taking part in this study?**

*[If there is no intended benefit]* This study is not designed to provide direct benefits to you.

Your *[insert condition]* may improve while you are in this study; however, this cannot be promised. The results of this study may help people with *[insert condition]* in the future.

# **Is there a potential conflict of interest for this study?**

The study is sponsored by *[insert sponsor name]*. *[Include applicable statement]*

There are no known investigator and/or institutional conflicts of interest for this study.

*[One/Several]* of the investigators involved in this research study receive(s) extra money from *[insert sponsor name]* that is not part of this study. These activities may include consulting, serving on advisory boards, financial investments in the company/drug, giving speeches, or writing reports.

# **If I decide to take part in this study, can I stop later?**

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Yes, you can decide to stop taking part in the study at any time. If you decide to stop, let your study doctor know as soon as possible. It’s important that you stop safely.

The study doctor may take you off the study if: *[remove any non-applicable bullet points]*

* Your health changes and the study is no longer in your best interest.
* New information becomes available and the study is no longer in your best interest.
* You do not follow the study rules.
* For women: You become pregnant while on the study.
* The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor, *[insert sponsor name]*.

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

# **What are the costs of taking part in this study?**

*[Choose appropriate drug or device section. This section must be customized by TGH OCR to align with relevant study documents. For example, drug may or may not be free to participants]*

## **DRUG**

*[Sponsor name]* will supply the *[drug name(s)]*, and will pay for research tests and procedures that are done only to collect research data. You and your insurance company/health plan will not be billed for the items and services that are being provided at no cost to you by the sponsor:

* *[provide itemized list of procedures and specific protocol visit occurrences so not to confuse with same service that is billable at other protocol visits]*

You and/or your insurance company/health plan will have to pay for the administration of the *[study drug name]*, all costs of your routine care that you would have received had you not participated in the study, and the costs of all additional care required by the study to manage your safety while you are participating in this study.

You will be responsible for co-payments and deductibles in the same way you would if you were not part of a research study. You will be responsible for any costs that your insurance company/health plan does not cover. You should check with your insurance/health plan to find out if the costs of care from being in this study are covered.

If you are a Medicare beneficiary and have opted for a Medicare Advantage plan to manage your health care needs, your bills while on this study will be sent to regular Medicare.

## **DEVICE**

*[Sponsor name]* will supply the *[device name(s)]*, and will pay for research tests and procedures that are done only to collect research data. You and your insurance company/health plan will not be billed for the items and services that are being provided at no cost to you by the sponsor:

* *[provide itemized list of procedures and specific protocol visit occurrences so not to confuse with same service that is billable at other protocol visits]*

You and/or your health plan/insurance company will have to pay for *[device name]*, the implant of the device, all costs of your routine care that you would have received had you not participated in the study, and the costs of all additional care required by the study to manage your safety while you are participating in this study.

You will be responsible for co-payments and deductibles in the same way you would outside of a clinical trial. You will be responsible for any costs that your insurance does not cover. You should check with your health benefit plan to find out if the costs of care from being in this study are covered.

## **TGH CHARITY CARE**

*[if applicable]* Tampa General Hospital provides necessary medical care regardless of the patient’s ability to pay for services. Charity care is available to all patients who are eligible, without discrimination.  Uninsured patients and patients without enough insurance coverage to meet their needs and who do not meet charity guidelines may qualify for discounted care.

If you need more information about your costs, please discuss with your study team, or call the TGH Financial Assistance Program at 813-844-8084.

# **Will I be paid for taking part in this study?**

*[If no compensation]* You will not be paid for participating in this study.

*[If compensation is provided]* You will be paid a total of *[insert dollar amount]* if you complete all of the requirements for this study. You will only be paid for visits that you complete. You will be paid for completing the following:

* *[Include specific requirement information and dollar amount for EACH time point where compensation if provided]*

*[Include information on how payment will be received, and any parties involved. If subjects are required to bring receipts to research sites, clearly outline the responsibility here]*

You may be required to complete a W-9 Form (tax form where you provide your name, address and Social Security Number) in order to receive payments. We will ask for your permission to share this information later in the consent form.

*[Must be included and customized as appropriate. If the study is for a “rare” disease, $600 should be updated to $2,000]*All study payments received are considered taxable income and reportable to the IRS. If your total payments exceed $600 in any one calendar year, *[insert sponsor or compensation vendor name as appropriate]* will file a 1099 (Miscellaneous Income) form with the IRS and will provide you with a copy of this form.

*[If commercial development is expected to arise from the study, include the following]*

Specimens taken from you are called your biospecimens. The findings from this research, which may include specimens taken from you or your biospecimens (even if identifiers are removed), may be used for the future development of products that are commercial value and/or profit. There are no plans to provide you with financial compensation or for you to share in any profits if this happens.

**What happens if I am injured because I took part in this study?**

You will get medical treatment if you are injured as a result of taking part in this study.

If you are injured or become ill as a result of your participation in this study, contact the Study Doctor, *[insert study doctor name]* at *[insert study doctor telephone number]* immediately.

*[For sponsored studies, language must align with contractual injury language and compensation]*

The Sponsor is obligated to pay for medical expenses incurred as the result of a Subject Injury. The term “Subject Injury” describes a physical injury or illness resulting from a side effect to or caused by the *Study Drug/Device* following its administration or use in accordance with the protocol. No other compensation of any type (for example, payment for lost wages, disability, or discomfort) will be provided by the Institution, Sponsor, or the Study doctor.

If the Sponsor pays for the medical expenses resulting from a Subject Injury, the Sponsor will be required to obtain your personal information in order to make these payments.

*[For investigator-initiated studies]* The cost of illness or injury that may result from your participation in research will be billed to your insurance company or to you in the event you do not have health insurance.  Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research.  You will be responsible for any unpaid amounts, deductible, co-insurance, or co-payments that result from such care.  *[For studies with USF PI]* If you are injured, the University of South Florida has not set aside money for lost wages, discomfort, or disability you may experience as a result of a research-related injury.  By signing this form, you acknowledge the University of South Florida will not pay for the costs of medical care and treatment, or any associated costs such as lost wages, due to injury arising from participation in this study. You do not give up your legal rights by signing this form.  In addition to contacting the study investigator, you should also contact the USF Institutional Review Board (IRB) at 813-974-5638 or RSCH-IRB@usf.edu if you believe you have been injured as a result of taking part in this study.

# **Who can answer my questions about this study?**

You can talk to the study doctor, *[insert study doctor name]*, at *[insert telephone number]* about any questions or concerns you have about this study or to report side effects or injuries.

*[Include for studies that are required to be posted to clinicaltrials.gov]* You can also get additional information 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.

*[Include if any IRB-specific contact information is given]*

In addition, if you have any concerns, complaints or questions about your rights as a research study subject, please contact:

*[insert IRB contact information]*

**Acknowledgment of agreement for use and storage of information**

In addition to this study, you have the option to allow us to use and/or disclose your protected health information for future studies. It is up to you to decide whether you want to agree to allow your health information to be used and stored for future research. You do not have to agree in order for you to take part in the study. *[Include a statement, if applicable, if subject must agree to genetic testing in order to participate]*

There is additional information about the use and disclosure later in this consent form. You are encouraged to read the entire consent form.

I agree to the choice(s) initialed below.

\_\_\_\_\_\_\_\_\_\_ I agree to provide *[blood/tissue]* for use in this research study.

\_\_\_\_\_\_\_\_\_\_ I agree to provide *[blood/tissue]* for future research studies.

\_\_\_\_\_\_\_\_\_\_ I agree to provide *[blood/tissue]* for genetic testing. *[If applicable]*

*[Include any payment method language here, subjects may opt-out of receiving payment, Greenphire clincard is an example]***GREENPHIRE CLINCARD:**

As mentioned in the “Will I be paid for taking part in this study?” section, in order to receive payment, you may be asked to provide your name, address, telephone number, and social security number. When payments are reported to the IRS, we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study, but you will not be paid.

After reading the below sentence, check “Yes” or “No” and initial next to your choice.

If you have any questions, please talk to your doctor or nurse. No matter what you decide to do, it will not affect your care.

 YES NO \_\_\_\_\_\_\_\_\_\_ I agree to release personal information such as my name, address, telephone number, and social security number for the purposes of receiving payments and for reporting my income to the IRS.

# **Research Authorization for the use and disclosure of protected health information**

**Study Title for Participants:** *[Insert Lay Study Title Here]*

Federal law requires that *[insert lead site name]* protect the privacy of information that identifies you and relates to your past, present, and future medical care conditions and payment for health care (“protected health information”). We are committed to protecting the privacy of your information.

If you choose to enroll in this research study, your protected health information (PHI) will be used and shared as explained below. This form helps you understand how your information may be used or disclosed in future. Please read the information below carefully before signing. By signing this form, you are permitting  *[insert lead site name]* to use and share your health information for research purposes.

**1. What protected health information will be used or shared with others?**

* Your research record including:
	+ Past research and medical records
	+ Current research and medical records
	+ Any future records collected during your participation in this study
* *[Include if applicable] Blood and tissue* specimens. If the specimen collection was optional, these specimens will only be shared if you have agreed to this in the consent form.
* *[List any other needed information not included above. The descriptions should have enough detail that one (or an organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.]*

**2. Who will use or share my protected health information?**

* The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
* *[For USF studies, where study procedures take place at TGH]* Members of Tampa General Hospital who are involved in this research study.
* Certain government individuals *[and university people]* who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
* The *[insert IRB review board name(s)]* Institutional Review Board (IRB) and their related staff who have oversight responsibilities for this study.
* *[List any internal compliance or data safety monitoring committees]*
* The sponsors of this study, *[insert sponsor name]*.

**3. Whom, outside of *[include lead site name]*, will my protected health information be shared with?**

Your protected health information may be shared with the following:

* The sponsor of the study, *[insert sponsor name]*
* Any agency of the federal, state, or local government that regulates this research. These may include: *[add/remove as appropriate]*
	+ Food and Drug Administration (FDA)
	+ Office for Human Research Protection (OHRP)
	+ Department of Health and Human Services (DHHS)
	+ *Other*
* Any laboratories, pharmacies, or others who are part of the approved plan for this study;
* All designated review committees such as:
	+ *[Add all that apply outside of the lead site: VA Research Services; etc.]*
* *[List any compliance or data safety monitoring committees]*
* Data Safety Monitoring Boards or others who monitor the data and safety of the study;
* There may be other people and/or organizations who may be given access to your personal health information, including *[List any other persons, classes of persons, and/or organizations. Do not list persons who are likely to change over the course of the study, instead list them by title or category only.].*
* Others as may be required by law.

Your identifiers may be removed from your private records or samples. Your information or samples could be used and/or given to another investigator for future research studies without getting additional consent from you.

*OR*

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

Anyone listed above may use consultants in this research study and may share your information with them. If you have questions about who they are, you should ask the study team. It is possible that the individuals who receive your health information for this research study redisclose your information, which means your information may no longer be protected by federal privacy laws.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

**4. Why will my protected health information by used and/or shared?**

* To conduct the research
* To analyze the study results
* To ensure that the study was done correctly
* It may be used to develop new tests, procedures, and devices/products

**5. How long will my protected health information be used or shared with others?**

There is no set amount of time for which your protected health information can be used or shared with others. This is because the information collected during the study may be analyzed for many years, and it is not possible for us to know when this will be done. Once your participation in the research has ended, your information will be stored in accordance with applicable policies and regulations.

**6. What are my privacy rights?**

You can refuse to sign this form.  If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change.

Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by local policies.

You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

* You will no longer be a participant in this research study;
* We will stop collecting new information about you;
* We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
* Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator

For IRB Study # *[Insert your Pro IRB Study #]*

*[Insert complete mailing address]*

**7. What if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

 *[Include a statement as to whether or not clinically significant results regarding the study or individual’s information will be disclosed to participants and how]*

*[Include # 8 If your project is* ***NIH-funded and collects identifiable, sensitive information,*** *as**it will be covered by an NIH Certificate of Confidentiality:]*

**8. Are there any special protections in place for my data privacy?**

This project is funded by the NIH and holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information, *[biospecimens]*, and records.  The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission.  Disclosure of your research information may only occur in limited specific instances.  [For mandatory reporters, include this statement:  For this study, the researchers may share your information with appropriate authorities if we learn about [include any legal requirements for abuse or public health reporting].]  For the full detailed description of the CoC protections and exceptions to those protections, please refer to the CoC Summary attachment at the end of this document.

*[If applicable (i.e. for studies involving surveys or interviews in which sexual violence or sexual harassment may be disclosed by a participant), include the following language.]*

A federal law called Title IX protects your right to be free from sexual discrimination, including sexual harassment and sexual violence. USF’s Title IX policy requires certain USF employees to report sexual harassment or sexual violence against any USF employee, student or group, but does not require researchers to report sexual harassment or sexual violence when they learn about it as part of conducting an IRB-approved study. If, as part of this study, you tell us about any sexual harassment or sexual violence that has happened to you, including rape or sexual assault, we are not required to report it to the University. If you have questions about Title IX or USF’s Title IX policy, please call USF’s Office of Diversity, Inclusion & Equal Opportunity at (813) 974-4373.

*[If applicable (i.e. for studies involving focus groups, include the following language]*

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

# **PARTICIPANT INFORMED CONSENT FOR CLINICAL RESEARCH**

**Study Title for Participants:** *[Insert Lay Study Title Here]*

**Participant’s (or Legally Authorized Representative’s (LAR) statement**

I have read this form (or it has been read to me). I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the study and authorize the use of my health information as outlined in the consent. I have received a signed copy of this consent form.

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Signature of Subject/Legally Authorized Representative Date

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Printed Name of Subject/Legally Authorized Representative

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Authority of Subject’s Legally Authorized Representative or Relationship to Subject

*(if applicable)*

**Statement of person obtaining informed consent**

I have carefully explained to the person, or his/her Legally Authorized Representative (**LAR**), taking part in the study what the patient can expect from his/her participation. I confirm that the participant or his/her LAR was given the opportunity to ask questions and has sufficient information to make an informed decision. This research subject or his/her LAR has provided legally effective informed consent.

**Assent (Minor between the ages of 7 and less than 18):** If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.

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

Signature of Person Obtaining Informed Consent Date

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Printed Name of Person Obtaining Informed Consent

**Witness Signature (If Required)**

* Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant’s (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).
* Other: I confirm that the consent discussion was appropriate for the participant’s (or LAR’s) understanding of the study.

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

Signature of Witness Date

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Printed Name of Witness

*[Delete page if not applicable]*

**Certificate of Confidentiality (CoC)**

**Summary Information**

This research holds a Certificate of Confidentiality from the National Institutes of Health.

***What is a Certificate of Confidentiality?***

With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify a research subject in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, (for example, if there is a court subpoena), unless the subject has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. A Certificate of Confidentiality does not prevent a research subject from voluntarily releasing information about them self or their involvement in this research.

***When are the researchers allowed by the CoC policy to disclose subject information?***

* If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

* If the subject has consented to the disclosure, including for medical treatment. If a subject wants their research information released to an insurer, medical care provider, or any other person not connected with the research, they must provide consent to allow the researchers to release it.

* If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

***When may the researchers disclose subject research information for this study?***

* [*Use the following language as applicable; edit as necessary, e.g., if the research is federally funded but isn’t subject to the requirements of the FDA, do not include the second phrase*.] If the *[enter name of federal or state agency],* the agency funding this research, requests information to audit or evaluate our procedures; *[or if we must disclose information in order to meet the requirements of the federal Food and Drug Administration (FDA)].*
* [Use the following language if you must disclose information covered by a Certificate, such as with potential child abuse, or intent to hurt self or others, in response to specific federal, state, or local laws*.*] The CoC will not be used to prevent disclosure of [list what will be reported, such as public health reporting, child or elder abuse and neglect, or harm to self or others], as required by federal, state, or local law. [NOTE: for non-mandatory reporters where the study population and/or focus of the research could result in learning about child/elder abuse, or harm to self or others, the researchers no longer have the option to disclose the information. Under the NIH CoC policy, non-mandatory reporters may not disclose this information.]

* [Use the following language if you intend to disclose information covered by a Certificate, with the consent of research participants*.*] The CoC will not be used to prevent disclosure for any purpose you have consented to, as described in this informed consent document. This includes [*briefly* restate what will be disclosed, such as including research data in the medical record].

**More detailed information about Certificates may be found at the NIH CoC kiosk:**

<https://humansubjects.nih.gov/coc/index>