

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

[Insert Study Number (if applicable), Insert Official Study Title, Insert NCT (if applicable)]

Investigator Information: *[insert name, address, and telephone number of principal investigator]*

Investigator 24-hour Phone Number: *[insert 24-hour phone number if more than minimal risk]*

Research Sites: *[insert research study sites]*

Sponsor: *[insert sponsor name]*

Protocol Number: *[insert sponsor protocol number]*

IRB Phone Number: *[insert IRB patient contact number]*

Office of Clinical Research: 813-877-2673 *[TGH CORE telephone number, remove if not applicable]*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

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.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because _____. *[Fill in the circumstance or condition that makes subjects eligible for the research.]*

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

IRB Approval Date

Document Revision Date: September 30, 2017

How long will the research last and what will I need to do?

We expect that you will be in this research study for _____ *[hours/days/months/weeks/years, until a certain event]*.

You will be asked to _____ *[include a high-level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]*

More detailed information about the study procedures can be found under *“What happens if I say yes, I want to be in this research?”*

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

[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study]

More detailed information about the risks of this study can be found under *“Is there any way being in this study could be bad for me? (Detailed Risks)”*

Will being in this study help me any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] This study may or may not provide direct benefit to you. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. *[First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]*

[Include for a study with no benefits to participation. Otherwise delete.] There may be no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. *[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]*

[Include 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.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: *[List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]*

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

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”). You may talk to them at **[Insert telephone number information for the IRB]** or **[Insert e-mail address for the IRB, if applicable]** if:

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

How many people will be studied?

We expect about _____ people here will be in this research study out of _____ people in the entire study nationally **[or internationally]**. **[If number of people at site is not known, it may be removed. The number of people in the study must be included.]**

What treatment will I get?

[If every person receives the same treatment.] Everyone in this study will _____. **[Insert study intervention]**

[Include for a clinical trial that do not involve randomization.] You will be assigned to a treatment group. **[Insert study groups and a description of the treatment associated with each group.]** Regardless of what group you are assigned to, the treatment you receive will be referred to as “study drug”.

[Include for a clinical trial that involves randomization. Otherwise delete.] You will be assigned to a treatment group. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ **[equal/one in three/etc.]** chance of being given each treatment. **[Insert study groups and a description of the treatment associated with each group.]** Regardless of what group you are assigned to, the treatment you receive will be referred to as “study drug”.

[For double-blinded research add] Neither you nor the study doctor will know which treatment you are getting. **[For single blinded research add]** You will not be told which treatment you are getting, however your study doctor will know.

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. 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 English units] 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 such*
- *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.*

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

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

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

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, ***[Describe the adverse consequences.]*** If you decide to leave the research, contact the investigator so that the investigator can ***[Describe the procedures for orderly termination by the subject, if any.]***

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. ***[Note: The consent document cannot give the subject the option of having data removed.]*** If you agree, this data will be handled the same as research data. ***[Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.]***

[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.]

Is there any way being in this study could be bad for me? (Detailed Risks)

[Delete this section if there are no risks or discomforts.]

[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.]

- ***[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 research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: _____ **[Omit the previous sentence if there are no known risks.]** The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. **[Omit the previous two sentences for research whose risk profile in pregnancy is well known.]** You should not be or become pregnant **[include as applicable “or father a baby”]** while on this research study.

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.

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. *[Add to this list other organizations that may have access to the subject's records such as the Food and Drug Administration, when the research is FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.]*

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

***[If genetic testing is performed, add]* 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.

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:]

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] 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.

[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. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.] 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.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described later on in this document.

[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.

Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include ***[describe reasons why the subject may be withdrawn, if appropriate.]***

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by ***[Insert name of sponsor]***.

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

[Include for research involving more than minimal risk. Otherwise delete.] ***[Insert the name of the institution]*** has no program to pay for medical care for research-related injury. ***[Describe any compensation available for research related injury.]***

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.

Option 1: Sponsor to Pay:

[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.

Option 2: SI billed to Insurance:

Also, for investigator-initiated studies with no SI coverage or indemnity by a funder] 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.

Will I be paid for taking part in this study?

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you _____ **[indicate amount]** for your time and effort for completed visits. **[Indicate if the amount is pro-rated for research visit completion.]**

[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 is 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]**

[If payment is being issued by TGH using Greenphire, add] Greenphire is a company working together with **[insert sponsor name]** to manage the reimbursement process. You will be issued a Greenphire ClinCard provided by **[insert sponsor name]**, which is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. You will be issued one card for the duration of your participation. If your card is lost or stolen a replacement card will be provided. Tampa General Hospital is not responsible for the funds received on the ClinCard. This funding is coming directly from **[insert sponsor name]**.

Also, you will have the option to receive updates related to payment alerts via text message (standard text messaging rates will apply) or email message. You will have the opportunity to opt-in to receive these messages. In order to send you the messages, Greenphire will need your cell phone number and/or e-mail address. You are not required to provide your cell phone or email address to be enrolled in the study or to use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. Text messages are automated and will be sent at no cost; however, costs to receive text messages vary by wireless provider and service contracts. Please refer to your telephone service contract for service to ensure there are no unforeseen costs related to receiving text messages.

In order for Greenphire to be able to reimburse you via ClinCard, Greenphire will need to collect information about you, including:

- Your Name
- Your Address
- Your Date of Birth
- Social Security number

This information will be collected from you by the staff at your study doctor's site.

[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 may be considered taxable income and reportable to the IRS. It is your responsibility to verify with your tax professional for filing of this income. 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.

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[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.

[Include for a clinical trial.] Instead of being in this research study, your choices may include: ***[include alternatives.]*** The important risks and possible benefits of these alternatives include: ***[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]***

[Include when applicable.] 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.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will/will not*** contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent.]

RESEARCH AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Federal law requires that *[insert lead site(s) name(s)]* 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(s) name(s)]* 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 medical records
 - Current medical records
 - Any future records collected during your participation in this study
- *[Include if applicable]* Any specimens or biospecimens (eg blood, urine, tissue, etc). *[If study include optional specimen collection, add]* 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.
- *[If multi-site study, add]* Members of *[include other site names]* who are involved in this research study.
- Certain government individuals 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 name]* Institutional Review Board (IRB) and their related staff who have oversight responsibilities for this study.
- The sponsors of this study, *[include sponsor name]*.

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

Your protected health information may be shared with the following:

- The sponsor of the study, *[include 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)
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- 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.

4. Why will my protected health information be 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?

[Include a statement regarding the length of time that data will be retained]

[If there is no set amount of time add] 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:

[Insert Principal Investigator Name and Address]

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

[Include for NIH-funded and collects identifiable, sensitive information]

7. 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, ***[include specimes/biospecimens, if applicable]***, 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. ***[NIH represented should provide site with CoC Summary which must be included as the last page of the consent form.]***

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

IRB Approval Date

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

Permission to Take Part in a Human Research Study

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative

Date

Printed name of legally authorized representative

Signature of person obtaining consent

Date

Printed name of person obtaining consent

IRB Approval Date

[Add the following block if you will document assent of the subject.]

Assent

- Obtained
- Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

- Parent
Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- The IRB determined that the permission of one parent is sufficient.
Second parent is incompetent
Second parent is not reasonably available
Second parent is deceased
Only one parent has legal responsibility for the care and custody of the child
Second parent is unknown

[Add the following block if you will document assent of children]

- Assent
Obtained
Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

[Add the following block to all consents]

Signature of person obtaining consent and assent

Date



Printed name of person obtaining consent

IRB Approval Date

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process