**VA Northeast Ohio Healthcare System IRB approved the use of this version on** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

# WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

You are being asked to participate in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_{*insert why this person is being asked to participate*}.  {*If* *the study is funded*} This study is funded by {*insert VA funding service and/or names of other funding organizations or commercial sponsors*}. By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*(If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following:* The purpose of this research is to gather information on the safety and effectiveness of \_\_\_\_\_\_\_\_\_\_\_\_ *{state name of drug, device, etc.}. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications.* )

# ****what does the study involve AND HOW LONG WILL IT LAST?****

***Briefly*** *describe the procedures to be followed in lay terms.*

Your participation in this research will last about {*state in hours, days, months, years*}.

*If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following:* The purpose of this research is to gather information on the safety and effectiveness of \_\_\_\_\_\_\_\_\_\_\_\_ *{state name of drug, device, etc.}. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications.*

*The following statement is required for FDA-regulated research:*

“Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research participants”.

# ****what are key reasons you might choose to volunteer for this study?****

State the most important reason(s) {i.e. potential benefit(s)} a person may want to volunteer to participate in this study?

# ****what are key reasons you might choose not to volunteer for this study?****

State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective. For a complete description of risks, refer to the Details in the Consent.

If *alternative treatments/procedures are key to the participant’s choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists/* For a complete description of alternate treatment/procedures, refer to the Details in the Consent.

# ****DO YOU HAVE TO TAKE PART IN THE STUDY?****

If you decide to take part in the study, it should be because you really want to participate. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

# ****what if you have questions, suggestions or concerns?****

The person in charge of the study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Principal Investigator, PI}*

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study *his/her* contact information is: {*PI contact information}*.

**RESEARCH DETAILS**

# WHAT IS THE PURPOSE OF THIS STUDY?

*In this section include why the research is being done. Ensure scientific language is explained in lay terms. Include if a drug or device used in the project has or has not been approved by the Food and Drug Administration for the specific use being evaluated in the project.*

With this research we hope to learn….

# HOW LONG WILL I BE IN THE STUDY?

*Explain in lay language how many subjects will participate in this study for this site and the duration of the individual’s participation in the study. Also state the length of time the study will last overall.*

This research study is expected to last approximately {X years, months, days}. Your individual participation in the project will take {X days, weeks, months, years}.

# WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

*Describe the procedures that will take place during the study. Clearly identify those that are experimental. Use lay terms and provide details.*

*Provide a detailed description and explain the participant’s time involved for each procedure or interaction, considering the following requirements:*

* *Provide a chronological explanation of the procedures that will be performed, distinguishing which procedures are experimental (being done solely for the purposes of the research, to include the use of investigational drugs and devices) vs. which are considered standard of care (for diagnostic or treatment purposes). Use a bullet outline or small paragraphs and subparagraphs to clearly outline what will happen in a step-by-step sequence.*
* *Use lay terms to describe medical terminologies (see* [*glossary*](https://www.portland.va.gov/research/documents/hrpp/glossary-of-lay-terms.pdf)*), e.g.:*
  + Catheter: a flexible tube for withdrawing or introducing fluids, put under the skin or into a vein using a needle; the tube may be left in for long periods after the needle used to insert it is removed.
* *Clearly indicate who is overseeing a procedure, the study team or the participant’s health care provider as part of usual care, so it is clear to the participant who is responsible for the following:*
  + *Providing the treatment or service*
  + *Monitoring the treatment or service as applicable*
  + *Defining whether adverse events result from usual care or research*
  + *Alerting the participant if there is a problem with the treatment or service*
  + *Documenting the participant’s clinical course while receiving the treatment or service*
* *For research involving randomization of participants into different study arms, specify the randomization process, explaining it in lay language, e.g. “*by chance.”
* *Include all the different people by study role with whom the participant will interact.*
* *Indicate when and where the study procedure(s) will be done.*
* *Specify how often the procedures will be performed and how long each will take.*
* *Indicate type and frequency of safety monitoring during and after the study.*
* *If applicable, include information regarding pregnancy testing for women of childbearing potential and indicate the frequency of the testing. If required for the study, birth control measures may be listed here.*
* *If the study includes surveys or questionnaires, include a statement that the participant is free to skip any questions that he/she would prefer not to answer.*
* *Include a full explanation of all responsibilities and expectations of the participant. You can include applicable points from the list below and/or add your own per study requirements:*
  + Take the study drug as instructed. *(If device, explain what is required for study compliance).*
  + Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
  + Tell the investigator or research staff if you believe you might be pregnant or if your partner might be pregnant.
  + Keep the study drug in a safe place for your use only and away from children
  + Fill out your diaries as instructed.
  + Complete your questionnaires as instructed.
  + Ask questions as you think of them.
  + While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.
* *If applicable, state if the participant will receive a general report of the aggregate results or any results specific to the participant (that are distinguished from significant new findings in Section 14 below).*

# WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

*Suggested wording that can be modified based on the type of research you are proposing to conduct:*  Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

* *Identify each intervention/procedure with a subheading and then describe any reasonable foreseeable risks, discomforts, and inconveniences, and how these will be managed. Include the probability of the risks, especially those that are likely and those that are rare but serious.*
* *In addition to physical/physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the study, to include risks inherent in genetic analysis and tissue banking if applicable.*
* *If there are any significant risks to participation that might cause the researcher to withdraw the participant or terminate the study, these should be described.*
* *Give measures which will be employed to minimize the described risks, discomforts, and inconveniences.*

*For studies involving possible reproductive risks, please include a section that includes the following:*

* *State any known risks in pregnancy, either to mother or child.*
* *State that there may be unforeseeable (unanticipated) risks to the participant (or to the embryo or fetus) if the participant is pregnant or becomes pregnant during the study.*
* *List the acceptable methods of birth control for this research study.*
* *Describe what action will occur in the event of pregnancy, e.g., follow-up of pregnancy outcome, immediate withdrawal from the study, etc.*
* *Describe if there is any effect on sperm count or the motility of sperm or other reproductive risks associated with fathering a child.*
* *Describe if there are any known risks to gametes.*

*Describe the known risks associated with the study drug, device, procedure, intervention, etc. Consider using the below headings, as applicable. There is no standard definition for the below categories, but could be defined as: Common, occurring greater than 20% and up to 100%; Occasional, occurring 4% to 20%; rare, less than 3%.*

1. **Common risks** *<state if some may be serious, e.g.* **(some may be serious)***>***:**

In 100 people receiving *<type or name of study drug/device/procedure>*, more than 20 and up to 100 may have:

*• <insert bullet point list of risks, and how serious each one is>*

1. **Occasional** *<state if some may be serious, e.g.* **(some may be serious)***>***:**

In 100 people receiving *<type or name of study drug/device/procedure>*, from 4 to 20 may have*:*

*• <insert bullet point list of risks, and how serious each one is>*

1. **Rare** *<state if some may be serious, e.g.* **(some may be serious)***>***:**

In 100 people receiving *<type or name of drug/device/procedure>*, 3 or fewer may have*:*

*• <insert bullet point list of risks, and how serious each one is>*

*Include the following information verbatim:*

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

*For common procedures (e.g. blood drawing, MRI), or if women of child bearing potential may be included in the study, use the following generally applicable statements as appropriate:*

* (1) Blood drawing

There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood.

* (2) MRI

Some people experience a 'closed-in' feeling due to the relatively restricted space within the MRI machine. You may not be able to have the MRI procedure if you have certain metal, surgical clips, or implants, including a brain aneurysm clip or a pacemaker, in your body, because during the MRI procedure metal can heat up and move, or clips and implants stop working. Dental fillings are not a problem. If there is any question about whether or not there is metal in your body, you may be requested to have an X-ray to determine this; the X-ray will become part of your medical record. If you are pregnant, you should delay having an MR scan. You will need to remove all jewelry or clothing with metal before having the MRI. All of these precautions will be reviewed with you immediately before you have the MRI.

* (3) Questionnaires

Some people become uncomfortable at being asked questions about \_\_\_\_\_\_\_\_; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

* (4) Photographs, audiotaping, or videotaping

*Choose either:  <*There will be no photographs, audio tapes, or video tapes made of you as part of this study.*> OR <* The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the VA Northeast Ohio Healthcare System while you are participating in this study.  You also authorize disclosure of the picture and/or voice recording to *<insert name and business address of every entity that xxx will release copies of the recording to>.* The said picture, video, and/or voice recording is intended for the following purposes: *<insert description of the purpose for taking the pictures>.*

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to stop being filmed, photographed or recorded, and may withdraw your consent for up to a reasonable time before the picture, video or voice recording is used.

*If the recording is an optional part of the study, such that a participant could refuse to be recorded but still be an active participant in the study, also insert the following:*

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* *(5) Inclusion of Women of Childbearing Potential*

*The policy of the FDA, the NIH, and other Federal agencies regarding the research participation of women with childbearing potential has changed substantially in the past few years. Studies are now mandated to include such women unless there is a clear and justifiable reason to exclude them. Studies involving investigational drugs should typically include the following statement in the RISKS section of the ICF:*

The safe use of *<drug name>* in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown. Women of childbearing potential enrolling in this study must (i) have been using a birth control measure (an intrauterine device (IUD), birth control pills, a condom, diaphragm, or abstinence) for the previous three months, (ii) must have a negative pregnancy test, and (iii) must agree to continue to use a birth control measure for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months. Nursing mothers may not participate in this study.

*For studies involving drugs that are known or suspected mutagens or teratogens (i.e., could cause birth defects), the potential benefit to the female participant of participating in the study must be weighed against the potential damage to a fetus.*

# WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

*This section must describe any potential direct benefits to the participant or to others which may reasonably be expected from the study. The description of benefits to the participant should be clear and not overstated in order to avoid the appearance of undue influence or coercion. If no direct benefit is anticipated, this should be stated. If study results will be given to the participant, this should be stated. List direct benefits, such as receiving an FDA-approved medication to treat a condition that would not otherwise be treated or being enrolled in one of two (both generally believed to be effective) counseling modalities not normally offered by the VA. Rule of thumb: if the VA offers the participant population any other effective treatment for the study condition, and/or if the study treatment is not FDA-approved to treat the study condition, and/or if there is a chance any participant will receive an ineffective placebo, enrolling in the study does not offer a direct benefit.*

***DO NOT*** *include any payment to be offered to participants for taking part. Not acceptable are statements that cite potential indirect benefits, such as receiving more intensive medical care, getting access to a potentially effective (investigational) medication, or being paid/ reimbursed travel costs/meals to participate.*

*Some examples on how to complete this section follow:*

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include *<list benefits>.*

***OR***

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

# WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

*If there are no alternative procedures/treatments to participating in this study, such as if the only alternative is not to participate in this study, this section should not be included in the informed consent form.*

*Describe alternative procedures or courses of treatment to participating in this study. To enable a rational choice about participating in the research study, individuals should be aware of the full range of options available to them, including palliative or comfort care (if applicable).*

*Example:* You may choose not to participate in this study. If this is your decision, there are other choices such as *<list alternatives, e.g. surgical treatment, lifestyle changes, etc.>.*

*If standard therapy is part of the research study, the participant must be told he or she can receive it outside of participation in the study, and state:*

You may discuss these options with your doctor.

# HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

*Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant’s privacy will be protected, and who may inspect the records.*

*For all studies that involve the collection of identifiable private information or identifiable specimens, include a statement on whether data or specimens if subsequently de-identified will be used for future research or not. One of the following statements should be used:*

*a.* Identifiers will be removed from the identifiable private information or identifiable biospecimens that are collected, After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative,

***OR***

*b.* Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

*If applicable, please provide a description of the Certificate of Confidentiality and any voluntary disclosure plan, or the potential for disclosures required by law, e.g., elder abuse, child abuse, study participants posing a danger to themselves or others, etc.)*

*Example:* We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

*If the study procedures have any implication on the patient’s care, the study team is required to put any details about the subject’s participation that are relevant to their care providers in the patient’s medical record. Therefore, for all studies that involve a medical intervention, you must include the following statement:*

We will include information about your study participation in your medical record.

*If the research is a clinical trial subject to FDA regulation, the following statement must be included:*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

While this study is being conducted, you (choose one)

will have access to your research related health records.

***OR***

will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care

and will not affect your right to have access to the research records after the study is completed.

# Health Information Portability and Accountability Act (HIPAA)

**Include the following language in GREEN verbatim: {IF IMPARIED DECISION MAKING INDIVIDUALS – REMOVE THIS WORDING AND SUBMIT A SEPARATE 10-4093 *HIPAA AUTHORIZATION FORM}***

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your ‘authorization,’ for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as **{MODIFY AS APPROPRIATE}** medical history, allergies, lab results, HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the **{MODIFY AS APPROPRIATE}**; **{ADD ENTITIES SUCH AS SPONSOR, CONTRACTORS, AFFILIATES AS APPROPRIATE}**; Institutional Review Board, Medical Research and Education Foundation (only if subject reimbursement is administered by the Foundation), Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **(insert name of Site Investigator)** and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked previously.

# WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

*Ensure there is a statement that veteran-participants will not be required to pay for care received as a participant in a VA research study such as the statement below:*

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

*If payment is being offered for participation in the study, a separate subheading (Financial Considerations) must be included with the following information. (If there is no payment being offered for participation, this should be so stated.)*

* *State whether the payment will be financial or something else such as a gift card, etc.*
* *If the payment is financial, describe the amount the participants will be paid, when payment is scheduled, how the payment will be disbursed, and the pro-rated amount the participant will receive should the participant decide to withdraw from the study or is withdrawn by the investigator.*
* *If the participant is reimbursed for certain expenses like transportation and parking, list the reimbursement rates.*
* *State who will be disbursing the payments. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. This information and the fact that the SSN of the subject will be used for this purpose must be included in the informed consent form.*

*Note: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care. Any payment offered should be commensurate with the time and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses.*

# WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

*If you sustain injury as a direct result of your study participation, medical care will be provided by the VA Northeast Ohio Healthcare System at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.*

*Example:* If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: *(List local site contacts)*

DURING THE DAY:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_and

AFTER HOURS:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Emergency and ongoing medical treatment will be provided as needed.

# DO I HAVE TO TAKE PART IN THE STUDY?

*State that participation is voluntary. Indicate that refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled.*

*Include this section if students, residents, or employees under the supervision of the investigators are included as research subjects*

If you are a student, resident, or employee of *(select all that apply and delete all others VA Northeast Ohio Healthcare System, UH, Case, etc.), your scholastic or employment evaluations will be conducted by a rater who is not involved with, and most likely totally unaware of this study. In no way will your job or position be affected by your decision to join or not join this study.*

*Explain any possible consequences of a participant’s decision to withdraw from the research. Describe any adverse effects on the participant’s health or welfare, or any extra follow-up that may be requested if the participant decides to withdraw from the study.* ***Explain the procedures for an orderly termination of participation. Such an explanation may be omitted if there are no adverse consequences to withdrawal.***

*Indicate that for data already collected prior to the participant’s withdrawal, that the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data. Also indicate that specimens already used cannot be withdrawn, if applicable.*

# RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

*Describe foreseeable circumstances under which the participant’s participation might be terminated by the investigator without regard to the participant’s consent. This section may be omitted if there is only a one-time intervention or there are no circumstances in which the investigator would terminate the participation of an individual participant.*

*If the investigator might terminate participation of a participant, possible reasons should be listed and the procedures for an orderly termination of participation described. Include a description of any adverse effects on the participant’s health or welfare that may result, or any additional follow-up that may be requested after the participant is withdrawn from the active portion of the study.*

# WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

**To answer questions about the research or if you sustain a research related injury contact the following**:

* During the Day: [include name and contact number]
* After Hours: [include name and contact number]

**For answers to questions about rights as a research participant or to voice a concern or complaint contact the following**:

* The Research Administrative Officer at (216) 791-3800 ext. 4657
* The VA Northeast Ohio Healthcare System Patient Representative at (216) 791-3800 ext. 1700

***Include the following statement verbatim:***  If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Institutional Review Board at (216) 791-3800 X4658 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

# WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

*State that new findings developed during the course of the research that may affect the participant’s willingness to continue participation will be provided to the participant. This section may be omitted if new information could not reasonably be used to alter participation (e.g., one-time interventions that are no greater than minimal risk).*

*Included a statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions.*

# WHO COULD PROFIT FROM THE STUDY RESULTS? (If applicable)

Describe any payments that are being made to investigators that could be construed as a potential conflict of interest. If a conflict of interest cannot be eliminated after the review by the IRB, the IRB may require that this section be included.

Include a statement whether specimens may be used for commercial profit and if subjects will share in the profit.

If a possible commercial product will be developed as part of this research, explain that the participant will not profit from any products or tests that might result based on research with their specimens.

# DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED? (If applicable)

*Include a statement whether the research might include whole genome sequencing.*

Describe in this section possible limits to individual confidentiality based on the technologies involved in the research. Clarify when and under what conditions research results of genetic testing will be conveyed to the participant, the participant’s family, or the participant’s physician.

Consider GINA language:

*Include the following statement verbatim, if applicable:*

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

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

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

# FUTURE USE OF DATA AND RE-CONTACT

If any of the participant’s data are going to be retained after the study for future research, the following information must be provided to the participant:

* Where will the data be stored
* Who will have access to the data

If the subject is going to be re-contacted in the future about participating in future research, this must be specified. Describe the circumstances under which the participant would be re-contacted whether within the VA or outside the VA.

# TISSUE BANKING (Include if Applicable)

*If you are planning to store blood, tissues, or specimes of any kind for future research, tissue banking guidelines must be addressed.*

*Describe where the specimens will be stored, who will have access to them, and how long they will be retained.*

*Clarify if, when and under what conditions research results will be**conveyed to the participant, the participant’s family, or the participant’s physician.*

*If tissue banking is an optional part of the study, give participants the choice of whether their tissue can be banked. For example:*

**Yes you may bank my de-identified tissues for use in other research.**

**No I do not give permission to bank my de-identified tissue for use in other research.**

You have the right to withdraw your consent in the future and have your unused specimen destroyed. You need to notify the investigator of your decision.

# AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

*The following language must be included verbatim unless otherwise indicated:*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(or you can indicate a study role that has been delegated by the PI to obtain informed consent)* has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this s*tudy (INSERT IF COMBINED WITH AUTHORIZATION VERBATIM)* “and authorize the use and disclosure of my health information for this study”. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. *Include if applicable:* A copy of this signed consent will also be put in my medical record.

|  |  |  |
| --- | --- | --- |
| **I agree to participate in this research study as has been explained in this document.** | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Signature | \_\_\_\_\_\_\_\_\_\_\_  Date |

***Additional Notes to Study Team Members:*** *Informed consent is a process, not just a form. The written presentation of information can be used as a teaching tool to document the basis for consent and for the participants' future reference. Obtaining informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.*

*The procedures used in obtaining informed consent should be designed to educate potential participants in language that they can understand. If an investigator proposes to use a participant population that does not speak or read English, a copy of the translated document, as well as the English version, needs to be forwarded to the IRB for approval.*

*For projects involving VA employees as participants investigators need to carefully review the template and not include any elements that may not pertain to these types of studies, such as statements involving usual care, alternate treatments, or current relationships with participant’s health care providers.*