**INSTRUCTIONS:** *The contents of this template are meant as a guide only. The descriptions provided in each section are included to assist in preparing an informed consent form that meets all VA and federal informed consent form and HIPAA authorization requirements. The research team must be cognizant of any state and local laws impacting on the informed consent process and include these requirements as well.*

**GUIDANCE:** *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 form should be revised when deficiencies are noted or when additional information will improve the consent process.*

1. *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 certified copy of the translated form, as well as the English version, needs to be forwarded to the IRB for approval.*
2. *Investigators must carefully review the template for projects involving VA employees as participants. Do 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.*
1. *When the participant population includes those with impaired decision-making, it is highly recommended to use separate consent and HIPAA authorization forms (10-0493).*
2. *No ICF may contain exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator or the Institution from liability for negligence.*
3. *The ICF must be written at an appropriate grade level for the group of participants, usually no higher than the 8th grade level based on an electronic grade level scoring system, which is available with most word processing systems. The IRB may consider higher reading grade levels based on the populations targeted in the study.* *Below are a few tips in reducing grade level:*
* *Use as few words with three or more syllables as possible.*
* *Break all compound sentences into separate short sentences.*
* *Use simple, declarative statements where possible.*
* *Change all passive voice sentences to active voice.*
* *Avoid using technical terms as much as possible. If technical terms must be used, explain what they mean in lay language.*
* *Treat events in chronologic order in the procedures section.*
* *Restrict descriptions of procedures to those things the participants will actually experience.*

**FORMATTING:**

* Complete the header with the requested information to include a version date. For multisite studies, both the PI of the multisite study and the local site PI must be listed.
* **Do not adjust the bottom margin**
* **In the footer change template information to ICF version number and revision date**
* **Do not remove text for Research Participant’s Initials in the bottom right corner of the footer. Per WSU IRB requirements, each page must contain research participant’s initials.**
* Read the guidelines for each section and then complete as applicable for your project. If using the guidelines as a template, please be sure and **delete the template guidelines, which are in red and blue print.**
* The ICF should be written in the second person, i.e., “You are invited to participate.”
* Phrases such as “I understand…” or “You understand…” are not allowed as they are inappropriate and may be interpreted as suggestive to constitute undue influence over a potential participant.
* Check for spelling, typographical, and grammatical errors.
* The ICF should include all the section headings indicated in the template unless otherwise indicated.

**KEY SUMMARY INFORMATION ABOUT THIS STUDY**

You are being invited to take part in a research study that is being funded by {*Insert VA funding service and/or names of other funding organizations or commercial sponsors.*} Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

*Provide a* ***brief summary of essential study information*** *under the headings below that individuals would want to know to make an informed decision about participation. Details will be provided in the next section. Limit this section to no more than one to two pages.*

**what is the STUDY ABOUT AND HOW LONG WILL IT LAST?**

***Briefly*** *describe the purpose of the study and the procedures to be followed in lay terms. Save more detailed descriptions for the Detailed Information section of this consent.*

By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about {*state in hours, days, months, years as applicable*}.

*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 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? For a complete description of benefits, refer to the Detailed Information section of this form.

**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 Detailed Information section of this form and/or Appendix.

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 Detailed Information section of this 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 volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

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

The person in charge of the study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Principal Investigator, as applicable}* at the {*insert name of VA* *facility.*} 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 as applicable}*.

***If feasible, such as there is less than half a page remaining, start a new page to begin the detailed section.***

**DETAILED INFORMATION ABOUT THE STUDY**

**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.*

By conducting this research project, 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 take approximately *{X years, months, days}.* Your individual participation in the project will take *{X days, weeks, months, years}.*

**WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?**

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

*Use a bullet outline or small paragraphs and subparagraphs to clearly outline what will happen in a step-by-step sequence including the time involved for the participant for each procedure or interaction taking the following issues into consideration as applicable:*

* *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*
* *Continue to use lay terms to describe medical terminologies.*
* *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 or like the flip of a coin.”
* *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.*
* *Indicate if there will be photographs, audiotaping, and/or videotaping. Explain how and why they will be used in the research and whether they will be disclosed outside of VA. If disclosed outside of VA, indicate to whom or what entity they will be disclosed. Also, include whether the subject can refuse to participate in this portion of the study and still take part in the rest of the study*

**WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?**

* *Include a full explanation of all responsibilities and expectations of the participant. Include applicable points from the list below and/or add study specific requirements:*
	+ Take the study drug as instructed. *{If device, explain what is required for study compliance}.*
	+ Keep the study drug in a safe place for your use only and away from children.
	+ 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 might have gotten your partner pregnant.
	+ Complete 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 the study team plans to request copies of medical records from outside non-VA facilities, state that here and indicate that a VA Form Letter 10-212 will need to be signed for each different non-VA entity from which records will be requested.*

*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 the significant new findings section later in this consent.)*

**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/drug/device with a subheading and then describe any reasonably 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.*

*Note: Consider using the following headings as applicable when describing risks for drugs, devices, and procedures:*

* *Common risks: In 100 people, from 20 up to 100 may experience these risks.*
* *Occasional: In 100 people, from 4 to 20 may experience these risks.*
* *Rare: In 100 people, 3 or fewer may experience these risks.*

*Studies are now mandated to include women of childbearing potential unless there is a clear and justifiable reason to exclude them. Studies involving investigational drugs should include a statement such as below as applicable:*

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.

*After the above or similar statement include possible reproductive risks below as applicable:*

* *State any known risks in pregnancy, either to mother or child.*
* *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.*

*Include the following suggested text or edit as applicable. The following section must address risks:*

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.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

*Describe any potential benefits to the participant or to others which may reasonably be expected from the research. The description of benefits to the participant should be clear and not overstated in order to avoid the appearance of undue influence or coercion.*

*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.* ***If no direct benefit is anticipated, this should be stated****.*

***DO NOT*** *include any payment to be offered to participants for taking part. Also, 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 condition(s).

 *If research results will be given to the participant, this should be stated.*

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

*Describe alternative procedures or courses of treatment. 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).*

*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 that he/she may discuss this option with his/her health care provider.*

*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.*

**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.*

*Example: Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:*

* + *Indicate how records are kept, e.g., locked in filing cabinets, on computers protected with passwords, who will have access, etc.*
	+ *For large multi-site studies, discuss the number and nature of the sites and what if any information will be shared among sites>>.*

*There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. (If the study involves a product regulated by the FDA, the Food and Drug Administration should be included in the above list)*

*For all studies that involve the collection of identifiable private information or identifiable specimens, include one of the following statements as applicable:*

* *A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such 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 the subject or the legally authorized representative, if this might be a possibility;* ***or***
* *A statement that the subject's 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, 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, the following statement must be included:*

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.

**Health Insurance Portability and Accountability Act (HIPAA)**

***This template (combined informed consent/HIPAA Authorization)* can only be used if both conditions are met:**

1. ***No optional banking of identifiable data or biospecimens is involved, and***
2. ***The IRB does not approve the use of subject’s legally authorized representatives (LARs) to consent for the subject.***

***If either of the above conditions are not met, a separate VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used.***

*Include the following language verbatim:*

There are rules to protect your private information. Federal laws and the federal medical or 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 these laws and the 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. While it is not the intent of this study, other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary or if there are interviews or surveys where you, as the research subject, provide that information to the research team. *(If your research study plans to collect any of this information delete the phrase “While it is not the intent of this study” and start the sentence with “Other Information”.)*

The research team may also need to disclose or share your information to others as part of the research and study progress. Others may include the following: ***{MODIFY AS APPROPRIATE:*** *VA Cooperative Studies Program (CSPCC); CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC’s Human Research Committee (HRC); Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate)l* the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

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

*Include the following language verbatim depending upon the choice made:*

While this study is being conducted you *(Choose one of the below to complete the sentence)*

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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you can ask a member of the research team to give you a form to revoke your authorization in writing. Your written request will be valid when the research team 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 which the research team has relied upon for the research and 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 prior to that time.

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

*Explain in lay language what the cost to participate will be, if any. 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 or your insurance 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 must be included with the following information:*

* *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 and whether the SSN of the subject will be used for this purpose.*

*If there is no payment being offered for participation, this should be so stated.*

*Note: 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?**

*Include the following statement verbatim:*

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

*Provide an explanation of whether any compensation is available or not should an injury occur and indicate that the participant does not give up any legal rights or release the VA from any liability by signing the form.*

*In addition, provide an explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained. Include specific information about whom the participant should contact in case of a research-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted.*

*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:

Dr./Mr./Ms. at and

AFTER HOURS:

Dr. /Mr./Ms. \_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

***For COVID-19 studies, the following language may substitute for the above language. This language cannot be changed by the study team.***

A new public health law under the Public Readiness and Emergency Preparedness Act (PREP Act) was issued by the Department of Health and Human Services on March 10, 2020. This law limits your ability to sue if you are in a COVID-19 research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP). For more information about this program, please contact the Health Resources and Services Administration’s CICP by phone at 855-266-2427 or online at https://www.hrsa.gov/cicp/about/index.html.

VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the local VAMC or arrangements may be made for contracted care at another facility. In case of research related injury resulting from this study, you should contact your study team. If you have questions about medical treatment for any study related injuries, you can call the operator at this VA Medical Center and ask for medical administration.

You still have the right to hold VA responsible for negligence that is not related to a COVID-19 study.

**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.*

*If the participant is a VA employee or student, indicate that refusal to take part in the study will in no way influence their employment, ratings, subsequent recommendations, or academic progress as applicable.*

*Also indicate that the participant may discontinue taking part at any time without any penalty or loss of benefits. If applicable, state that the participant may withdraw and still receive the same standard of care that he or she would otherwise have received.*

*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.*

**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?**

*Explain whom participants should contact with any questions, complaints, and concerns about the research or related matters. Contact information for the investigator should be included for questions about the research.* ***At least one of the contacts must be someone other than the investigator or other study personnel such as the local Patient Advocate****. Make sure you inform all persons listed that they are points of contact for participants and ensure they are knowledgeable concerning the study. Document the contact as part of your research records.*

***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 *{INSERT LOCAL IRB NAME/CONTACT}.* This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the *{INSERT LOCAL IRB CONTACT}* 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? *(Include if applicable)***

*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).***

*Example:* Sometimes during the course of a research study, new information becomes available about the <<treatment/drug>> that is being studied that might change a person’s decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

*Also, include 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? (Include 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, 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.

DOES THIS STUDY INVOLVE GENETIC RESEARCH AND HOW WILL MY GENETIC INFORMATION BE PROTECTED? (Include 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.

*Include the following Genetic Information Nondiscrimination Act (GINA) language 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 (Include if applicable)

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 specimens of any kind for future research, tissue banking guidelines must be addressed. Submit a separate HIPAA Authorization 10-0493.*

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

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

*Explain if the participant will be re-contacted after the original project is complete. In addition to the above, specify why the tissue is being banked and the potential future uses.*

***If participants will be given a choice of whether tissue can be banked, an example of how this can be done is below. Note: A separate HIPAA Authorization must still be completed – use the VAIRRS 7.3A Informed Consent template without the HIPAA Authorization.***

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

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

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

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study *(Omit the second half of this sentence if a separate HIPAA authorization VA Form 10-0493 will be completed.)*  You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. *(Include if applicable:* A copy of this signed consent will also be put in your medical record.*)*

|  |
| --- |
| **I agree to participate in this research study as has been explained in this form.** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant’s Signature | \_\_\_\_\_\_\_\_\_\_\_Date |

*Note: The use of a witness signature is optional. If the IRB determines that a witness signature is required, an additional line for the witness signature must be added below the participant’s signature line. Usually, a witness is solely witnessing the signature of the participant but the IRB may determine that the witness must witness the entire consent process. A note should be added below the signature of the witness indicating what the role of the witness is.*

*IMPORTANT: The below signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide signed informed consent and a signed HIPAA Authorization. Only use the LAR signature block in place of the participant’s signature block if it has been explained in the new study application (subject to approval by the IRB) that these types of populations are going to be used in the study). Delete this if you do not plan to enroll participants using an LAR.*

|  |
| --- |
| **The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of Legally Authorized Representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Legally Authorized Representative | \_\_\_\_\_\_\_\_\_\_Date |
| **Indicate below your authority to act as the participant’s legally authorized representative to both sign this informed consent form on the participant’s behalf and to authorize access, collection, and use of the participant’s protected health information in this research project under the HIPAA Privacy Law:**[ ]  Spouse[ ]  Parent[ ]  Adult Child (18 years of age or over) for his or her parent [ ]  Adult Sibling (18 years of age or over)[ ]  Grandparent[ ]  Adult Grandchild[ ]  Guardian appointed to make medical decisions for individuals who are incapacitated[ ]  Other per local or state law Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

*NOTE: If a local site has local or state policies in regard to other signatures or annotations on the informed consent form, these should be documented as part of the local site investigator application and these changes justified within the application.*