*INSTRUCTIONS for this VA Informed Consent Form Template:*

1. Once finished with preparing the informed consent form for a specific study, DELETE THIS INSTRUCTION SECTION. *NOTE: The consent form should begin with the heading* “WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?”
2. Required items - All items in the template must be included in the Informed Consent Form (ICF) unless the instructions indicate otherwise (e.g., “required only if applicable”). Please do not change the order of the items in the template.
3. **Entering text -** In the body of the ICF you may either: (1) type directly, (2) copy and paste text from another document, or (3) insert an existing text file. As new text is entered, new form pages will be created automatically to accommodate the added text. *Any* **blue text** *within greater/less than symbols (< >) should be replaced with study-specific text and the symbols removed from the final ICF.* All text in the final document should be black.
4. ***NOTE:*  if this is a multi-site study,** the consent form should only cover the VAPORHCS research activities (research conducted while on VA time, utilizing VA resources (e.g., equipment), or on VA property).
5. **Remove Instructions/Notes in *red italics***prior to submission to the IRB. Item numbering should also be removed (place the cursor within the numbered item and click on “numbering” on tool bar).
6. **Page numbering -** Page numbering is automatic.
7. **Header and Footer** - To complete the header and footer, select “View” in the toolbar at the top of your screen, then “Header and Footer.” Because the footer is different on page 1, a section break was required, which means that the header and footer need to be edited on both pages 1 and 2 for the information to be correct on all following pages. The ICF version date assigned by the PI (not the template version) must be indicated in the right-hand side of the footer. Each change to the ICF, whether substantive or administrative, requires an update of the ICF version date to the current date. Do NOT update the “Research Service Template Version Date.”
8. **Section headers -** Do not end a page with a section header. If there is not room to begin text after the header, insert a page break before beginning the new section.
9. If specimens and/or data will be contributed to a Tissue and/or Data Repository (i.e., specimens or data will be banked for future research)**,** complete the **ICF Template Addendum: Banking your <** **human biological specimens/data> for Future Research** at the end of the ICF Template. If the sole purpose of the research is to collect data or biological specimens for a tissue bank/data repository, incorporate the addendum into the main body of the ICF and delete all the sections that are not applicable
10. The HIPAA authorization is a separate form from the ICF. Template can be found at:

<https://www.va.gov/portlandresearch/documents/hrpp/10-0493-fill.pdf>

# *IMPORTANT NOTES REGARDING ADDITIONAL REQUIREMENTS:*

* **ICF Revisions -** Any revised ICF must be approved by the IRB prior to use.
* ***Per signed PI Assurances:*** 
  + *Unless the IRB has granted a waiver of all informed consent/authorization requirements, or a waiver of documentation of informed consent, I assure that I or a qualified research staff member will:*
  + *Create a progress note within 24 hours containing all required elements in the Electronic Health Record (e.g., CPRS, CERNER), when appropriate* ***(see VAPORHCS IRB P&P/SOP)****.*
  + *Give a copy of the informed consent form to each participant.*
  + ***Forward/provide each original signed consent form and signed HIPAA authorization as soon as possible, preferably within three (3) business days of obtaining consent to the Research Compliance Officer (RCO) for review. I will keep a copy until the original is returned and will then maintain the original on file (as applicable).***
  + *Activate an electronic research flag for all patients consented in this study unless the IRB determines that this requirement does not apply to my study. If participants do not meet enrollment criteria, the flag will be removed.*
  + *Maintain a master list of all consented subjects; this list will include participant’s names and the date(s) of their informed consent and, if applicable, reconsent.*
  + *If the study involves the enrollment of non-Veteran subjects, or Veterans who may not be enrolled in VHA healthcare, I will obtain a signed VA FORM 10-0483 (i.e. Notice of Privacy Policy acknowledgement form located at*: <https://vaww.va.gov/vaforms/medical/pdf/vha-10-0483-fill.pdf> *) from each non-Veteran and/or Veteran (if applicable) who provides informed consent to participate in the study. I will then forward/provide the signed VA Form 10-0483 along with the signed ICF and HIPAA authorization (if applicable). I will keep a copy until the original is returned and will then maintain the original on file (as applicable)*.

**WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

About the research, call <name> at <phone number>. *If you give the name and number of the PI, be sure someone will always be available to answer at that number. Consider whether a research coordinator would be a better contact, or give more than one contact.*

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call <name of PI or responsible clinician> at <phone number>.

*If applicable include following statement:*

Other research team members include <name(s)\* or study position title(s) of study staff with whom the patient is likely to have contact (e.g., study coordinator or co-investigator who will obtain consent, administer a questionnaire or procedure or perform an intervention)>***.***

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VAPORHCS Privacy Officer at (503) 273-5037.

*INSTRUCTIONS: SUMMARY OF KEY INFORMATION*

*This section introduces participants to the research study.*

*Note: This new section complies with new requirements in the Final Revisions to the Common Rule, which are in effect as of January 21, 2019. More information about the revised Final Rule is available at* [*https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)

*The Final Rule requires* ***“that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.”*** *This section includes the “five factors” identified in the Final Rule that “would encompass the key information,” including providing a brief description of key foreseeable risks.* ***NOTE:*** *The information in this section must be presented in a way that does not merely provide lists of isolated facts, but rather facilitates comprehension. This section should not exceed 3.5 pages.*

**SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**

**WHAT AM I BEING ASKED TO DO?**

We are asking you to take part in a research study that is being funded by <insert funding agency(ies); e.g., the Department of Veterans Affairs>. We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases.

We are asking you to take part in this research study because <reason e.g., you have asthma, or you have had a stroke.>

**TAKING PART IN THIS STUDY IS YOUR CHOICE**

You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form <and the authorization>. However, to participate in this study, you must sign this consent form <and the authorization>.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered.

**WHY IS THIS STUDY BEING DONE?**

***Briefly*** *summarize the study’s* ***primary objective****.*

***EXAMPLE:*** *This study is being done to answer the following question: Can we lower the chance of your prostate cancer growing or spreading by adding a drug to the usual combination of drugs? We are doing this study because we want to find out if this approach is better or worse than the usual approach for your type of cancer. The usual approach is defined as care most people get for prostate cancer.*

**WHAT IS THE USUAL APPROACH TO MY <INSERT – type of condition, diagnosis, etc.>?**

***If applicable to the study include this section.*** *Provide a brief description of a usual approach, which should not be overly specific or detailed, allowing the research to be placed into context. Indicate whether the usual approach includes FDA-approved treatments. Include an estimate of the expected outcome of the usual approach when/if it is known. Avoid naming specific drugs as these could change with the availability of new treatments, except where a particular drug(s) is so commonly accepted that it provides the easiest explanation.*

***EXAMPLE:*** *The usual approach for patients who are not in a study is treatment with medications for nausea and vomiting that have been approved by the Food and Drug Administration (FDA).*

***EXAMPLE: (behavioral studies)*** *The usual approach for patients who are not in a study is to get advice from their doctor. This advice might include ways to exercise and how to do their daily activities so they are less tired.*

***EXAMPLE:*** *The usual approach for patients who are not in a study is treatment with surgery, radiation, or drugs, (indicate if FDA-approved). Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer. The usual approach is proven to help patients with your health condition live longer.*

**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

***If applicable to the study include this section.***

* You may choose to have the usual approach described above.
* You may choose to take part in a different research study, if one is available.
* *Include if appropriate.* You may choose not to be treated for <insert condition, disease, etc.>
* *Include if appropriate.* You may choose to only get comfort care to help relieve your symptoms and not get treated for your <insert condition, disease, etc.>.

**WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?**

*Briefly summarize in a bulleted list or short paragraph the major study procedures, test, exams, and the time commitment/duration (on active treatment, receiving the intervention and in follow-up). Specifically indicate if any test(s) include(s) genetic testing.*

***EXAMPLE:*** *If you decide to participate, you will be asked to have several tests and procedures including:*

* *Study drug daily (1 pill daily)*
* *Five blood draws*
* *CT scan every 3 months*
* *Optional cheek swab for genetic testing*

***EXAMPLE:*** *Your participation in the study will consist of <XX] visits over [XX days/weeks/months>. Visits will last up to <XX minutes/hours/days>. We may ask to follow your health through <medical record review/follow up phone calls> for up to <XX weeks/months/years>.*

***EXAMPLE:*** *If you decide to take part in this study, you will get <insert description of intervention, e.g., study drugs or study approach> for up to <insert intervention length>.*

***EXAMPLE:*** *If you decide to take part in this study, you will either get <insert description of intervention, e.g., study drugs or study approach> for up to <insert intervention length>, or you will get <insert description of intervention, e.g., study drugs or study approach> for up to <insert intervention length>.*

***EXAMPLE:*** *After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 3 months for 2 years after treatment. After that, they will check you every 6 months for 3 years. This means you will keep seeing your doctor for 5 years after treatment.*

A detailed description of all <procedures/test/exams/questionnaires/surveys/blood draws/etc.> that will be done as part of this study is located below in the “What will happen during this study?” section.

**WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?**

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

**RISKS**

We want to make sure you know about a few key risks right now however we provide more below information in the “What are the risks and possible discomforts from participation?” section.

*Briefly summarize the most important (most common, most severe) expected risks of participation. Do NOT include a copy and paste of all the risks from the main consent.* ***NOTE:*** *See the “What are the risks and possible discomforts from participation?” section in the main consent form template below for additional boilerplate risks statements that may be more appropriate to move to this Key Summary section.*

***EXAMPLE (studies that include collection of data from subjects’ entire medical records and/or includes data that may be considered sensitive information):*** *This study involves collecting information directly from your medical record. OR; This study involves collecting sensitive information from you about <insert type of information>. OR; <You may be asked sensitive or private questions about things you normally do not discuss.> The research team will make every effort to protect your information. However, a loss of privacy could occur. If there is information in your medical record <or about you> you do not want shared you should consider this risk before agreeing to take part in this study.*

***EXAMPLE (studies that include genetic testing/analysis and/or studies whose primary objective is genetic research:)*** *Some members of your family may not want research done on your tissues to understand the genetics or possible inherited disorders of you and your family. This may cause conflict with your family members and could affect your decision or the decisions of family members to have children. You may want to hold a discussion with your family members before agreeing to take part in this study.*

***EXAMPLE (studies that include high level of time and/or possible travel commitment for critically or terminally ill patients):*** *This study may require you to spend more time in the hospital or clinic <many required study visits, long hospital stay, need for several days lodging nearby, etc.> and result in loss of time otherwise spent with family, friends, or other activities and commitments. You should consider your time and what things are important to you before agreeing to take part in this study.*

***EXAMPLE (studies that include high level of time and/or possible travel commitment for subjects/patients in general:)*** *Taking part in this study may mean you need to make more visits to the clinic or hospital. As a result, you may have more travel or personal costs and/or need to take time off from work.*

***EXAMPLE (studies that include investigation drug(s)) with reproductive risks:*** *This study involves a study drug(s) that could harm a fetus and requires all subjects to use a method(s) of birth control that work(s) well. If you are opposed to using any or all forms of birth control (for any reason), you should speak to the study doctor before considering taking part in this study.*

**BENEFITS**

*Summarize any reasonably foreseeable/potential benefits of participation.*

***EXAMPLE:*** *You will not directly benefit from taking part in this research.*

***EXAMPLE:*** *This study is not likely to help you. However, it may help the study doctors understand how this study drug works. This study may help the study doctors learn things that may help other people in the future.*

***EXAMPLE (Phase 1 Studies):*** *There is some evidence in people with <insert disease or condition> that adding <insert study drug/intervention/treatment> to the usual approach can stabilize <insert disease or condition> for longer than the usual approach alone. However, we do not know if this will happen in people with your type of <insert disease or condition>. It is unlikely that adding <insert study drug/intervention/treatment> to the usual approach will help you live longer than the usual approach alone. This study may help the study doctors learn things that may help other people in the future.*

***EXAMPLE (Phase 2 and 3 Studies):*** There is evidence that this *<insert study drug/intervention/treatment> is effective in treating <insert disease or condition>. However, it is not possible to know now if the* *<insert study drug/intervention/treatment> will effectively treat your type of <insert disease or condition> compared to the usual approach.* This study will help the study doctors learn things that will help people in the future.

**IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

Yes, you can decide to stop taking part in the study at any time. If decide to stop taking part in the study, and you are a Veteran receiving medical care from VA Portland Health Care System, you will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

***If applicable to the study include the language below.***

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

*Indicate what will happen if a subject chooses to withdraw from the research study and the procedures for orderly termination of participation by the subject (e.g., list the visits and/or procedures the subjects will be requested to complete.) If withdrawal from a research study may have deleterious effects on the subject’s health or welfare, explain any withdrawal procedures necessary for the subject’s safety and state why they are important to the subject’s welfare.*

***EXAMPLE:*** *If you decide to stop, let your study doctor know as soon as possible. It’s important that you stop safely. This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your health etc. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.*

**ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?**

*Clarify under what circumstances the subject’s participation may be terminated by the investigator without regard to the subject’s consent (e.g., investigator’s discretion, sponsor’s discontinuation, pregnancy, serious side effects, progression of disease, failure to respond to treatment, subject’s failure to comply with instructions, etc.). An unexplained statement that the investigator and/or the sponsor may withdraw subjects at any time does not adequately inform the subject of the circumstances of withdrawal.*

***EXAMPLE:*** *Yes. The study doctor may take you off the study if:*

* *Your health changes and the study is no longer in your best interest.*
* *New information becomes available, and the study is no longer in your best interest.*
* *You do not follow the study rules.*
* *For women: You become pregnant while on the study.*
* *The study is stopped by the study sponsor, <insert name>. the study sponsor is the organization who oversees the study.*

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor or nurse.

**WHAT IS THE PURPOSE OF THIS STUDY?**

*Describe in simple language the purpose of the study, using language such as the following:*

The purpose(s) of this study is to learn about a new drug called <name of drug> that may help in treating <health issue>.

*If the study involves a procedure, describe in simple language and give the name of the procedure using language such as the following:.*

This study involves a new surgery called anastomosis that might be helpful in treating strokes. Anastomosis means <explain in lay terms>.

*If the study includes genetic analysis, include the following:*

The purpose of the study is <also> to understand the inheritance of <disorder>. If a gene or genes that cause(s) <disease/disorder> can be identified and characterized, the diagnosis and treatment of <disease/disorder> may be improved. Genes are the units of DNA, the chemical structure that carries your genetic information which decides many human characteristics, such as the color of your eyes, your height and whether you are male or female.

As part of this study, <blood, tissue, saliva, etc.> obtained from you will be used by researchers to sequence all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

**OR**

<blood, tissue, saliva, etc.,> obtained from you as part of this study, will not be used by researchers to sequence all or part of your DNA (genomic sequencing).

*If the study includes investigational integral biomarker(s) which are essential for conducting the study:*

Another purpose of this study (**OR:** The purpose of this study) is for the study doctors to learn if a <insert name of biomarker being tested for> test is helpful to decide <insert purpose of biomarker test, e.g., which study group you will be in>. An <insert how biomarker sample will be obtained, e.g., extra tube of blood will be drawn or tissue from your surgery will be used> for the test. The study doctors do not know if using the test is <adapt and insert as appropriate based on statistical design: better, the same, or worse> than not using the test.

*If the study includes a component where information and/or human biological specimens will be contributed to a repository (i.e., will be stored for future research purposes), please complete the addendum at the end of this template.*

* *For any repository contribution that is an* ***optional component of study participation*** *(i.e., individuals may still participate in the study if they choose not to contribute), use the addendum as presented.*
* *For any repository contribution that is a* ***required component of study participation****, merge the information from the addendum into the main portion of the ICF instead.*

*If the study includes optional research procedures, not related to optional banking of data/specimens (i.e., included in the Banking Addendum).* The optional procedures should be clearly identified as such in the “What Will Happen During This Study?” and “What Are the Risks …?” sections of the ICF.  For example, “OPTIONAL:  You will also be asked to <describe optional procedure(s)> for this study.  It is not necessary to complete <this/these> optional procedure<s> to participate in the rest of the study.”

*Include any other purposes that may apply to this research study (e.g., production of medical products, etc.)*

*If applicable, specify that an investigational (experimental) device, procedure or drug is to be used. If a Phase I, II or III study, include the applicable NIH definition below.*

In Phase I clinical trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In Phase II clinical trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

In Phase III studies, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

# DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

*If an investigator involved with this research study does have a conflict of interest in the research study, as defined in the VA Portland Health Care System Conflict of Interest in Research Form, include the following:*

<Investigator’s name> <receives payments for lecturing for and/or has an equity interest in and/or receives royalty from a patent associated with and/or serves in an executive position with> <Sponsor name>, a sponsor of this research study. This conflict has been reviewed and managed by the VAPORHCS Conflict of Interest in Research Committee.

*If any investigator on the study may also be the patient’s health care provider, include* *the following paragraph*:

<Investigator name> is a researcher on this study and may also be your health care provider. They are interested in both the clinical welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

# HOW MANY PEOPLE WILL PARTICIPATE?

Approximately <number> people will participate in this research study at the VA Portland Health Care System.

*If a multi-site study, include the following:*

Additionally, about <number> people will participate at <number> other sites across the <state, United States, world, etc.>, for a total enrollment of <number> people at all sites.

WHAT WILL HAPPEN DURING THIS STUDY?

***Describe succinctly and in chronological order the study procedures that the subject is expected to complete for research purposes only and specify any procedures that are experimental.***

*Procedures done for research purposes include additional clinical visits, x-rays, blood draws, questionnaires, surveys, dosages of a drug, surgical procedures, etc. that will only be done to meet the study goals. Use language such as the following:*

The <procedures/questionnaires/surveys/blood draws/etc.> will be done for research purposes and will not be completed if you decide not to take part in the study.

***When applicable****, clearly identify any activities that are usual (i.e. standard) care and whether the researcher or the subject’s health care provider is responsible for: 1) explaining risks and benefits, 2) providing and monitoring the treatment or service, 3) defining whether adverse events result from usual care or research, 4) alerting the subject if there is a problem with the treatment or service, and 5) documenting the subject’s clinical course while receiving the treatment or service.*

*Include an estimate of the time required to complete each research procedure and the amount of time required for each appointment. If procedures are complex, provide a simple table showing what procedures will occur at each study visit. If blood is to be drawn, indicate the amount in lay terminology (e.g., 4-5cc = 1 teaspoon, 15cc = 1 tablespoon).*

*Example:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Visit 1  Day 1 | Visit 2  Day 14 | Visit 3  Month 3 | Visit 4  Month 6 | Visit 5  Month 12 |
| Screening tests and medical history | X |  |  |  |  |
| Blood draw  (1 Tablespoon.) | X | X | X | X | X |
| Chest x-ray | X |  |  | X | X |
| Quality of Life Questionnaire | X |  |  | X | X |
| Total time | 4 hours | 30 minutes | 30 minutes | 3 hours | 3 hours |

*If applicable, include how the experimental/research procedures differ from standard of care. Use language such as the following:*

The <procedure/treatment> is not the same as your current health care because <indicate explicitly what is different (e.g., you will receive the drug more often, you will have more frequent visits, the drug dosage will be different, this procedure is experimental, etc.)>.

*If there will be a placebo arm in the study, use language such as the following.*

In this study, some people will receive the real study drug, and some will receive a fake drug called a placebo. A placebo is a pill or solution that tastes, looks and smells like the study drug but has no real medicine in it. A placebo is sometimes called a “sugar pill.” The placebo being used contains <contents of the placebo>.

***NOTE****: If a sham procedure is used, clearly state that the procedure may or may not involve the actual treatment.*

*If applicable, indicate how patients are assigned to different treatments or conditions. Use language such as the following.*

This is a randomized study. That means neither you nor your doctor can choose whether you will receive the study drug or the placebo. That will be decided by chance (like tossing a coin, heads could mean you get the study drug and tails that you get the placebo). You have a <insert proportion> chance of getting the study drug in this study.

*Indicate whether patients or doctors will know what treatment patients are receiving (single/double-blind). Use language such as the following.*

You and the studydoctors/nurses will not know which pill (or dose) you get. The study is done this way because sometimes knowing that you are getting the test drug can change the results of the study. Also, sometimes people get side effects from placebos. Even though no one will know which pill you will get in this study, if you start having serious side effects, for your safety, the study doctors can find out if you are getting the test drug or placebo. Please ask the study doctor for more information if you have any questions about this kind of study.

***If this study includes collection of human biological specimens, describe how the specimen(s) will be collected, and inform the subject how long the specimens will be used and/or stored.***

*If the intent is to store the specimens indefinitely, make this clear. If the intent is (also) to bank specimens for future research, please complete the addendum at the end of this template or merge the language from the addendum into the main ICF, as per the instructions in the “What Is the Purpose?” section above.**Use language such as the following.*

Your <describe the human biological specimens> will be used only for this research and will be destroyed immediately after they are analyzed.

***OR***

Your <describe the human biological specimens> will be stored only for this research, which is expected to last until <end date>, and then the <describe the human biological specimens> will be destroyed.

***OR***

Your <describe the human biological specimens> will be stored <for (duration) or until (date)> and will then be destroyed.

***OR***

<If you agree,> Y/your <describe the human biological specimens> will be stored indefinitely <for use in future research>.

*If any x-ray or radioactive material is part of the research study, the Radiation Safety Officer is required to review your protocol. Contact the Radiation Safety Officer (x55853) for advice and documents.*

***If questionnaires, surveys, diaries, or other data collection tools will be used, state what kinds of questions are being asked and how long the tasks will take to complete; also, submit a copy of each tool along with your consent form.***

*If HIV non-confirmatory tests, (such as rapid saliva testing) are performed for the study. Use language such as the following.*

As part of this study, you <may/will> <describe procedure for obtaining specimens>. Your <specimen type> will then be tested to see if you may have human immunodeficiency virus (HIV). If the results are positive, we will provide you with further information regarding HIV. If you are a VHA patient and have positive results, we will also offer to provide a referral for <a> further blood test<s> to verify the HIV results. Any VHA providers who access your medical record would be able to see such a referral, which will indicate the positive results from the study test. You will be asked to provide a separate consent for any such additional HIV testing.

*If HCV and/or HIV serologic confirmatory tests are performed for the study. Use language such as the following.*

As part of this study, you <may/will> have <amount of blood> drawn from a vein in your arm using a needle. The blood will be tested to see if you have <hepatitis C (HCV) and/or human immunodeficiency virus (HIV)>. If the results are positive, we will provide you with further information regarding <HCV and/or HIV>. <List appropriate entity – e.g., the analyzing lab or the study team> is required to report positive results for <HCV and/or HIV> blood tests to the State of Oregon Public Health Division. Per VA requirements, you will be asked to provide a separate, verbal consent before a HIV blood test can be performed. If you provide this consent, it will be documented in your medical record, and your blood will be tested for HIV. If you refuse, your blood will not be tested for HIV <, and you will not be eligible to participate in this study>.

**WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?**

***Methodically describe reasonably foreseeable risks, side effects, discomfort, and inconveniences related to the research. Identify any procedures, etc. that are usual/standard care and who will explain any risks associated with that usual care, separate from the research risks. Include common risks, as well as severe adverse outcomes, that have a low probability of occurrence.***

In addition to the risks described above in the Summary of Key Information About This Study, “What are the risks and benefits of taking part in this study?” section, the following risks could occur if you choose to take part in this study.

*If the study includes investigational drugs, devices, and/or procedures, a risk statement(s) must be included. Use language such as the following.*

You may have some side effects we do not expect because we are still learning about <type or name of drug/device/procedure>.

Here are important points about side effects:

* The study doctors do not know who will or will not have side effects.
* Some side effects may go away soon, some may last a long time, or some may never go away.
* Some side effects may interfere with your ability to have children.
* Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

* Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
* The study doctor may be able to treat some side effects.
* The study doctor may adjust the study drugs to try to reduce side effects.

***Drug Risks:* *Include risks of the drugs that are the focus of the investigation and comparator medications.***

*The text for each risk section below should be taken from the VA Form 10-9012 form and translated into lay language. Contact the Research Pharmacy at* [*VHAPOR-ResearchPharmacy@va.gov*](mailto:VHAPOR-ResearchPharmacy@va.gov) *or x55543 for further assistance regarding translating text from the 10-9012 into lay language.*

***The risks of each drug used in the study should be described in order with the following three headings:***

*“Definitions of frequency categories:*

* *“Common, some may be serious” - There is no standard definition of the frequency of risks included in this category however, as a guideline, “Common, some may be serious” can be viewed as occurring in greater than 20% and up to 100% of patients receiving the drug/agent.*
* *“Occasional, some may be serious”- There is no standard definition of the frequency of risks included in this category however, as a guideline, “Occasional, some may be serious” can be viewed as occurring between 4 and 20% of patients.*
* *“Rare, and serious” - Side effects that occur in less than 3% of patients do not have to be listed unless they are serious, in which case they should appear in the “Rare, and serious” category. This categorization will need to be modified for prevention studies.*
* *“Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, or life-threatening.”*

COMMON, SOME MAY BE SERIOUS

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

* *<insert bullet point list of risks>*

OCCASIONAL, SOME MAY BE SERIOUS

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

* *<insert bullet point list of risks>*

RARE, AND SERIOUS

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

* *<insert bullet point list of risks>*

*If the study includes “statin drug(s)” a risk statement under,* ***Rare but Serious Risks*** *heading must be included. Use language such as the following.*

***NOTE:*** *Assure the phone # you list is always answered and that the doctor or an alternate doctor can be reached in a timely fashion. Use language such as the following.*

Researchers think another drug that is like <indicate drug name> might cause a serious disorder called rhabdomyolysis, which is the destruction of skeletal muscle cells. When they are destroyed, parts of these cells go into the bloodstream. This sometimes causes pain and may cause kidney failure, which can be fatal. If you start to have any muscle pain, pain in the calves or lower back, weakness, tenderness, fever, dark urine, nausea or vomiting, **you should call <PI or Responsible Clinician> at <phone number> immediately.**

*For studies involving any of the antidepressant drugs listed below for the treatment of worsening depression or the emergence of suicidal tendencies, include the 2 following paragraphs. The antidepressant drugs include: Prozac (fluoxetine); Zoloft (sertraline); Paxil (paroxetine); Luvox (fluvoxamine); Celexa (citalopram); Lexapro (escitalopram); Wellbutrin (bupropion); Effexor (venlafaxine); Serzone (nefazodone); and Remeron (mirtazapine).*

Some people with depressive illnesses such as yours have thoughts of wanting to harm or kill themselves. You may continue to feel this way until you recover fully from the illness. Even though antidepressants improve depression in many people, some patients experience worsening depression and/or anxiety while on medication. If you develop any symptoms, including increased depression or new or increased suicidal thoughts during this study, you should contact Dr. <name> at <phone number> immediately.

Some warning signs of worsening depression include worrying and becoming upset more than normal; having feelings of fear; being unable to sleep or needing less sleep; and being grumpy or angry. Other signs include greater activity and fast speech, wandering off the point during conversation, having grand ideas, and making poor choices.

*For potential drug interactions, a risk statement must be included whenever a study involves the administration of medications that may interact with several other medications*. *Use language such as the following.*

There are several drugs (prescription and non-prescription) that may cause problems when taken with the study drug. <PI or Responsible Clinician name> will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell <PI or Responsible Clinician name> before you take the new drug. You could also have your provider talk to <PI or Responsible Clinician name> before prescribing the new drug. **Do not take any new over-the-counter drugs or herbal or dietary supplements** while you are in this study unless you first check with <PI or Responsible Clinician name>.

*For pregnancy/risk to fetus. Use language such as the following.*

***(For Women):***

You should not become pregnant while participating. If you are or become pregnant, <drug, treatment, procedure> is known to affect a fetus in the following ways <list known effects on pregnancy, if any> OR < omit this statement if there are no **known** risks.> The <drug, treatment, procedure> could affect a fetus in ways that we do not yet know about. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use one or two methods of birth control that work well, like birth control pills, a patch, long-acting progestins, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell <PI or Responsible Clinician name> and your doctor immediately.

***(For Men):***

You should not cause a pregnancy while participating in this study. The <drug, treatment, procedure> is known to affect a fetus in the following ways <list known effects on pregnancy, if any> OR <omit this statement if there are no **known** risks.> The <drug, treatment, procedure> could affect a fetus in ways that we do not yet know about. If you are a sexually active male and can cause a pregnancy (insert if applicable <even if you have had a vasectomy,>) you must be sure that you and your female sexual partner(s) use(s) a method of birth control that works well, like birth control pills, a patch, long acting progestins, an IUD, or a diaphragm with spermicide, or you must use a condom with spermicide during sexual intercourse. A vasectomy is <not> an acceptable method of birth control. You must do this the whole time you are in this study. If a sexual partner becomes pregnant during the research study, please tell <PI or Responsible Clinician name> and your doctor immediately.

***Include the risk of inducing malignancy, if applicable to the study.***

***For Studies that will use tissue collected and released directly to the research team without Pathology & Laboratory Medicine Service (P&LMS) examination. For guidance, please see the tissue for research policy located at:***[*https://www.va.gov/portlandresearch/documents/crcresources/tissue-for-research.docx*](https://www.va.gov/portlandresearch/documents/crcresources/tissue-for-research.docx)

*Use language such as the following.*

As part of this study, a piece of your <type of biospecimen> will be released to <study doctor, researchers of this study, company, affiliate, etc.> without examination by the VAPORHCS Pathology & Laboratory Medicine Service (P&LMS). This could result in a diagnosis of cancer or other serious health issue(s) to be missed.

*Include the risks of a breach of confidentiality or an invasion of privacy. Invasion of privacy reflects access to a person’s body or behavior without consent; confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. A breach in confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, etc.) as well as economic harm (e.g., if a social security number were used by someone to gain access to a bank account or credit card through identity theft). Specifically, consider and address the risk of breach of confidentiality or psychological trauma. Use language such as the following.*

Information that identifies you will be used in this study and shared with <study sponsor, research staff, non-VA researchers, etc.>. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting <*list applicable risks:* e.g., ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.>

*If the study includes possible psychological risks, a statement must be included (e.g., the impact of learning results if no effective therapy exists or on plans to have children).**Use language such as the following.*

As a result of participation in this study, you may learn information <describe information that could be learned> that could be upsetting to you. If you are upset about the results learned during the course of the research study, Dr. <PI or, as applicable, Responsible Clinician name> may refer you to a counselor.

***List and explain any procedures to be done for research purposes only.*** *Use language such as the following.*

The following research procedures are in addition to those you would receive for your current health care.

*For blood draws:*

You may feel some pain from the needle when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

*For x-rays, DEXA scans, and other exposures to radiation for diagnostic purposes, please refer to the Radiological Procedure Chart at* [*https://www.va.gov/portlandresearch/piservices/rd\_forms.asp#alphabetical*](https://www.va.gov/portlandresearch/piservices/rd_forms.asp#alphabetical) *to determine the figure that should be inserted for the Background Equivalent Radiation Times (BERT). Explain over what time period the radiation in your study is given, such as if the amount described here is over the entire course of the research study, annually, etc. Please contact the Radiation Safety Officer if additional questions arise on how to complete this paragraph.*

In this study you will be exposed to radiation during the <name of the procedure>. Radiation is measured in units called millirems (mrems). All human beings are constantly being exposed to naturally occurring background radiation at a rate (depending on where you live) of about 300-360 mrem per year. During the time you are enrolled in this research study, <list the procedure(s)> will expose you to a total of about <#> mrems, about the same as you would be exposed to in <total BERT>.

*If the study includes fluoroscopy exposure, risk statements must be included as well as a radiation exposure statement (see above) . Use language such as the following.*

The duration of your fluoroscopy exposure is typically <enter number of minutes>. If used for longer than 60 minutes in one area, fluoroscopy can cause temporary hair loss, reddening of the skin, blistering or ulceration in the area of exposure. This would usually occur 14 to 21 days following exposure. If this occurs, please contact <PI or Responsible Clinician> at <phone number>.

*Include* ***ONE*** *of the following statements for any procedures involving radiation.*

No increased risk has been scientifically demonstrated from this level of exposure, though a very small increase in cancer risk may exist.

***OR***

The amount of radiation you will be exposed to is the same as you would receive in treatment. There is an increased risk <e.g., of cancer> with the radiation; however, joining the research study will not increase your risk.

***OR***

There is an increased risk, <e.g., of cancer>, with the amount of radiation to which you will be exposed; however, <explain and justify the risk>.

*If the study includes MRI(s), a statement must be included. In addition, be sure to check with imaging service about any possible concerns regarding the use of MRI in conjunction with the patient population that this project recruits. Use language such as the following.*

**For MRI:** The magnetic resonance imaging (MRI) machine is a powerful magnet. During the MRI, you will be exposed to a magnetic field that is strong enough to cause some metal in your body to move or heat up. If you have metal objects in your body (for example, a Cerebral Vascular stent, metal fragments in your eye, tattoos on your head or eyelids, non-removable hearing aids, nerve stimulators, or pacemakers), you will not be allowed to enter the magnet area and you cannot participate in this component of the study. If you know of any metal in your body, you should tell us right away. Review any dental treatments you have had with <insert appropriate team member name>, since these may involve metal. During the scan you will be able to see the doctors or technicians performing the test, and you will be able to speak to them through an intercom. The most common discomfort of an MRI is the length of time you must lie still or flat while the scan is being performed. Some people with claustrophobia (fear of closed spaces) may find the MRI machine too confining. Finally, the MRI scanner makes loud beeping or thumping noises, so you may be offered protective earplugs to wear during the scan.

*If the study includes MRI(s) with contrast, a risk statement must be included. Use language such as the following.*

The dye that is injected into your body has been used in many patients and is generally well tolerated. Some people feel dizzy or queasy, get a headache or notice a cold feeling near the site where the dye is injected. There is also a chance of having an allergic reaction to the dye that very rarely can be serious and life-threatening. If you have kidney disease, there is a chance that the dye could cause nephrogenic systemic fibrosis (NSF). NSF is a disease in which too much scar tissue forms, leading to serious damage to skin, muscle, and internal organs, and, in some cases, death. If you have kidney disease or think your kidneys may not be functioning properly, you should discuss this with <PI or Responsible Clinician> before any dye is injected.

*If the study includes indwelling catheter(s), a risk statement must be included that*  describes the *specific amount or a range of time the catheter will be in place (e.g.,* *more than 24 hours, less than 48 hour.). Use language such as the following.*

You will have a catheter (tube) in your vein for <amount of time>. You could get an infection where the tube is placed. This would cause swelling, redness and pain. You may bleed or get a bruise. There is a small chance your blood stream or heart valves might get a serious infection. You may get a blood clot that could go to your lungs. These problems are very rare. If you have these problems, you will need hospital care.

*If the study includes endoscopy, a risk statement must be included. Use language such as the following.*

You will be given a drug to relax you, and it may make you drowsy. Then, a tube-like instrument called an endoscope will be placed down your throat. This procedure, called an endoscopy, may make you gag or feel queasy, or it may give you a sore throat. There is a small chance that your esophagus, stomach or small intestine may bleed. You may get an infection. About once out of every 5,000 endoscopies, an endoscopy causes a hole in someone’s esophagus or stomach. If this happens to you, you may need to have surgery to repair the hole. Since you may feel drowsy because of the drug, you should not drive a car or operate machinery for 24 hours afterwards.

*If the study includes bone marrow biopsy, a risk statement must be included. Use language such as the following.*

During a bone marrow biopsy, some cells are taken from inside your bones. To do this, we will numb an area of your skin with a shot. Some people (fewer than one in 10,000) are allergic to this kind of shot. If you are allergic, you may experience some of the following symptoms: <explain possible allergic reactions>*).* After numbing, we will insert a long needle into your bone near your hip to get the cells. The shot may cause a little pain. You may also feel a great pain when the cells are drawn in through the long needle. Your hip may hurt for about three to six days. There is a small chance you will get a bruise or an infection where the needle is inserted. You may bleed or have a scar. Your skin may itch. These problems are rare.

*If the study includes other types of biopsies (skin, muscle, fat, etc.), risk statement(s) must be included. Use language such as the following.*

Taking a biopsy means removing a small piece of tissue. For this biopsy of your <body area>, we will give you a shot to numb the area. Some people (fewer than one in 10,000) are allergic to this kind of shot. If you are allergic, you may experience some of the following symptoms: <explain possible allergic reactions>. After numbing, we will make an incision (a cut) to take out the tissue. Heavy bleeding from <skin, muscle, fat, etc.> biopsy is rare. Biopsies cause infections about 10% of the time. A small scar will form at the biopsy site. The scar is usually much smaller than the original cut, and it sometimes is almost invisible.

*If the study includes surgery that is NOT investigational, a risk statement must be included. Use language such as the following.*

You are invited to be in this research study because you are scheduled to have <name of procedure>. You have already consented to this surgery. The surgery is not experimental and is not part of this study. The risks of <name of procedure> have already been discussed with you, and a copy of that consent form should be given to you.

*If the study includes populations at risk of suicide, include the following statement.*

If you should ever express thoughts of wishing to harm yourself or considering suicide, we may call the National Suicide Prevention Hotline and/or the Veterans Crisis Line and transfer you to that call.

*For studies involving interviews/questionnaires/Quality of Life (QOL) assessments that discuss sensitive issues (any questioning that could evoke negative or troubling emotions or create uncomfortable circumstances), the risk of emotional upset must be described, and subjects must be informed that they may refuse to answer questions that upset them.* *Use language such as the following.*

Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

*For research as part of this study or for future research using these samples or data, genetic data that may be shared in a public database (e.g., per the NIH Genomic Data Sharing Policy), a risk statement must be included. Use language such as the following.*

Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

The Genetic Information Nondiscrimination Act (GINA), a federal law, generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more employees to discriminate against you based on your genetic information.

* 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.
* However, there is a serious risk, if there is a loss of confidentiality and certain genetic information reaches your current or future life, disability, or long-term care insurance carrier, your employer (if s/he employs fewer than 15 employees), or others, that you or members of your family may experience some type of discrimination resulting in (1) **loss of life insurance, disability insurance, or long-term care insurance coverage** **and/or** (2) **loss of job**. All researchers associated with this study will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists, despite every reasonable effort. If you have any questions, please ask <PI>, who can be reached at <phone number>.
* The VAPORHCS also abides by the Oregon Genetic Privacy law (ORS 192.531 through ORS 192.549) and its requirements concerning confidentiality and the legal remedies provided by that law for breach of its requirements. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the VA Regional Counsel office at (503) 412-4580.

**HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

*If applicable, indicate how information and/or human biological specimens will be used and/or shared outside the VAPORHCS and confidentiality protected.* ***Please include all applicable options below:***

***The following statement******MUST BE INCLUDED******for studies using identifiers, regardless of whether specimens and/or information may be shared outside the VA.***

Identifiers related to you (i.e., information that can identify you) will be used in this research study and will include: <*include any of the 18 HIPAA identifiers that will be used as part of the study*>. These identifiers may be used to obtain information about you <and/or your health (if applicable)> from VA records <and from the health information sources listed on the HIPAA authorization (if applicable)>.

***The following statement******MUST BE INCLUDED******for studies using identifiers, regardless of whether specimens and/or information may be shared outside the VA.***

In the future, identifiers may be removed, and de-identified information and/or biospecimens about you used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

*For identifiable human biological specimens and/or information shared outside VA. Use language such as the following.*

<*Information/specimens*> related to you will be shared with other researchers as part of this study and will include the following identifiers that may identify you or your family members: <*include any of the 18 HIPAA identifiers that will be used as part of the study*>.

*For coded (i.e., linkable, by the study team, back to the subject identity) human biological specimens and/or information shared outside VA. Use language such as the following.*

Your <information/specimens> will be shared with other researchers as part of this study. A code number will be assigned to your <information/specimens>. Only personnel for this study will be authorized to link the code number to you. Other researchers who may receive your <information/specimens> will be given only the code number and will not be given any other information to link the code back to you.

*For de-identified (i.e., not linkable by the study team or others back to the subject identity) human biological specimens and/or information. Use language such as the following.*

Your <information/specimens> will be shared with other researchers as part of this study. All personal identifiers (such as initials and date of birth) will be removed before they are released to any other researchers. Once that happens, the study personnel and other researchers will not have information to link the <information/specimens> back to you.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the <information/specimens>, unless you provide written permission or unless otherwise required by law.

*If any information that is identifiable (such as signed informed consent forms, or coded data plus linking information) will be disclosed, stored or shared outside of the VAPORHCS, as either hard copy or electronic files, one or both of the following two paragraphs (as applicable)* ***MUST BE INCLUDED****.*

***NOTE:*** *Transfer of ownership language is only to be used when transferring data to a coordinating center for a multi-site study. Once ownership of a copy of the data is transferred, work on that copy of the data can no longer be done on VA time, in VA space or using VA resources.*

Ownership of a copy of the following information <list specific: identifiers, including dates of visits; information; forms; etc.> will be transferred to <specify individual, agency, company, affiliate, etc.> and will be the responsibility of <specify individual and/or PI at the receiving agency, company, affiliate> and <specify individual, agency, company, affiliate, etc.>.

By signing this informed consent, you give permission for the transfer of a copy of the following data: <include this information if you are not transferring ownership and not using the paragraph directly above>, to <specify where, i.e., locked file cabinet in a locked office located at <specify physical or virtual location>, OHSU network drive, REDCap\*, etc.> at <specify individual, agency, company, affiliate, etc.>. <Specify individual, agency, company, affiliate, etc.> and <specify individual and/or PI at the receiving agency, company, affiliate> will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared outside the VA may no longer be protected under federal law*.* Research records may be reviewed and/or copied by the sponsor.

*If study includes the use of OHSU REDCap. Use language such as the following.*

The <describe information that is completed in or stored, such as study tests> in a database called REDCap. The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU). Information about you will <described whether or not subjects will be identifiable, the type of identifiers or how identity will be concealed>. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

*If video/audio tapes or photographs are being used for research purposes, the following statements* ***MUST BE INCLUDED****, and indicate whether or not subjects will be identifiable, or how identity will be concealed. Indicate whether or not photographs, videos, and/or audio recordings will be disclosed outside the VA and, if they will be, include to whom they will be disclosed (as applicable).*

The <photograph, digital image and/or audio recording> will be produced while *<describe the activity or situation>* for the purpose(s) of <describe how the image and/or recording will be used>. By signing this consent form, you authorize the use of the *< photograph(s), digital image(s), and/or video or audio recording(s)>* for research purposes.All research-related <video/audio tapes or photographs> will be held in accordance with the VA records control schedule.

*If this project will be protected by a Certificate of Confidentiality (CoC), include a statement that the study has a Certificate of Confidentiality and, if applicable, describe the type of information that will be included in the subject’s VHA medical record.* ***NOTE:*** *The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included in informed consent documents describing Certificates of Confidentiality. Such statements should be included in the CoC statement below if not already included in the template language.*

To help us further protect your privacy, we have obtained a Certificate of Confidentiality from the National

Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States

Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

*Modify as appropriate.*

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document <state what will be disclosed, such as *the type of information that will be included in the subject’s VHA medical record>.*

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child or elder abuse, communicable diseases, or harm to self or others.

*If study involves interviews, questionnaires, surveys, or other procedures during which such information may be learned, the following statement* ***MUST BE INCLUDED.***

**Mandatory reporting of suspected child, elder, or vulnerable adult abuse.** Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

*If study involves clinical trial of drugs or biologics (other than Phase I investigations) or device trials, the following statement* ***MUST BE INCLUDED.* *NOTE: The PI is responsible for registration on clinicaltrials.gov.***

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

*If study involves a drug, medical device or biologic regulated by the FDA, the following statement* ***MUST BE INCLUDED.***

This study involves <a drug, device or biologic> regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

*The following statement* ***MUST BE INCLUDED.***

**Possibility of Disclosure and Notice of Privacy Practices.**

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at <http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048>).

***For Studies Enrolling Non-Veterans or Veterans who are not enrolled in VHA health care:***

*All the regulations pertaining to the participation of Veterans as research participants, including requirements for indemnification in case of research-related injury, pertain to non-Veterans or Veterans who are not enrolled in VHA health care participants enrolled in VA-approved research. Once approval from the RDC has been received, non-Veteran participants and Veterans who are not enrolled in VHA health care must be treated in the same manner as Veterans who are enrolled in VHA health care. However, in addition to signing the ICF and HIPAA authorization (as applicable), each non-Veteran and Veteran who is not enrolled in VHA health care participant must also be provided with a copy of the VA Notice of Privacy Practices, as well as sign VA Form 10-0483: Acknowledgement of the Notice of Privacy Practices (*<https://www.va.gov/portlandresearch/documents/hrpp/10-0483-fill.pdf> *). The signed VA Form 10-0483 must be submitted to the Research Administration Office with the signed ICF and HIPAA authorization (if applicable).*

*For Studies Enrolling Non-Veterans or Veterans who are not enrolled in VHA health care, the following statement* ***MUST BE INCLUDED.***

If you are a non-Veteran, we will provide you with the VA Notice of Privacy Practices and ask you to sign the acknowledgment (VA Form 10-0483) you received the document. This acknowledgement may be scanned into your medical record.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?

*A statement informing subjects whether you will disclose research findings of any kind (e.g., results of genetic studies, clinically relevant information, or incidental findings) to the subject or their provider(s)* ***MUST BE INCLUDED.******NOTE:*** *If the subjects are not informed in the consent document that they may be re-contacted, any attempt to re-contact the subject by the researcher must first be approved by the IRB.*

***DESCRIBE THE FOLLOWING:***

* *The disclosure procedures (e.g., who will make the disclosure and to whom; as appropriate, any requirement for repeat testing and/or plan for referral to a genetic counselor or other professional for appropriate medical advice), and*
* *Any risks associated with receiving this information (e.g., psychological risks, impacts on insurability, employability, family plans, and family relationships, and costs of additional medical care and testing).*
* *Lab results to be shared with subjects or their providers.* ***NOTE:*** *Lab results that are shared must be obtained in a CLIA-approved lab.*

***EXAMPLE (for sharing results):*** *We will give <you, your primary care provider, etc.> the results of your <describe tests; e.g., research blood tests, CT scan, genetic tests, screening tests>. The results will be placed in your medical record.*

***EXAMPLE (for incidental findings):*** *We do not plan to share your <research, genetic, other as applicable> test results with you or your primary care provider. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory. You may learn information about your health that is upsetting or that impacts your <family planning, family relationships, ability to get insurance, career, other as appropriate>.*

***EXAMPLE (for research MRI or other imaging):*** *The MRI scan is being done to answer research questions, not to examine your brain for medical reasons.  This MRI scan is not a substitute for a clinical scan (the type a doctor would order).  The research scan may not show problems that may be picked up by a clinical MRI scan. If we find an abnormality that requires urgent follow-up, we will contact you and your doctor (with your permission) to help answer questions and get the right follow-up care for you.  It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.*

***EXAMPLE (recommended language for sharing genetic results):*** *Because genetic information is complex and sensitive, the results should be discussed with a genetic counselor or your primary care provider who can answer your questions or discuss your concerns. You would be responsible for all costs associated with having the test repeated and visiting a doctor or genetic counselor to discuss the results.*

***EXAMPLE (for anticipated secondary findings):*** *The research tests in this study may tell us that you are at risk for <condition>. If we find out that you are at risk, we will contact you and refer you to <provider that can help with condition>. You would be responsible for all costs associated with any follow-up testing and medical care.*

***EXAMPLE (If no disclosures are to be made, explain why):*** *The results of research tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.*

***EXAMPLE (If no disclosures are to be made, explain why):*** *The results of research tests will not be made available to you because the results will be general and not relate directly to you and/or your medical care.*

**WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

*A statement regarding cost to subjects* ***MUST BE INCLUDED.*** *Use language such as the following.*

**Participants.** A VA participant will not be required to pay for care and services received as a subject in a VA research project.

None of the participants will pay for any of the following because they are only for research study purposes:

<list applicable procedures, etc.>

Some Veterans are also required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

***NOTE:*** *If the study includes non-Veterans, they will need to either pay for standard care costs, or their insurance will need to be billed. A statement to this effect* ***MUST BE INCLUDED.***

You would receive the following <treatments, procedures, etc.> even if you were not in this study because they are part of the standard clinical care for your condition and are not part of this study: <specify applicable treatments, procedures, etc.>.

WILL I BE PAID FOR PARTICIPATING?

*If participants will be compensated for participation, or for expenses associated with participation, indicate*

*how the subject will be compensated, the schedule for receipt of compensation, the amount of compensation, and how the amount will be prorated if the subject withdraws before completing the study. A statement to this effect* ***MUST BE INCLUDED.*** *Use language such as the following.*

You will be paid $<amount> for each <indicate study related procedure - e.g., blood draw/session> that you complete. You will receive the <cash, check, etc.> payment at the end of each <indicate study related procedure >. If you drop out of the study before completing all the <indicate study related procedures >, you will be paid for the <indicate study related procedure> that you completed. If you complete all of the scheduled <indicate study related procedure >, you will have received a total of $<amount>.

***NOTE:*** *If applicable, delineate travel reimbursement from compensation for participation payment(s) and clarify that subjects will not receive dual travel reimbursement for a given day (e.g., beneficiary travel with qualifying medical appointment and travel reimbursement for research visit on same day).*

*If study will use Electronic Funds Transfer (EFT) or checks for participant payment(s), The following statement* ***MUST BE INCLUDED***  *(remove references to any form of payment not used in this study).*

Participants of this study will receive payment in the form of a check or electronic funds transfer (EFT). This will require the of use your Social Security Number to process the payment. To receive payment by EFT, you will also be required to provide banking information for payment purposes. Your banking information will not be used for research purposes. An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY?

*If the study collects/banks biospecimens, even if identifiers are removed, the following statement* ***MUST BE INCLUDED.***

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to an individual, the federal government or a private entity. There are no plans to provide financial compensation to you should this occur. However, should the VA ever provide your samples for research or commercial use, it will do so in such a way asto protect yourprivacy and confidentiality as stated in the CONFIDENTIALITY section of this document.

**WHAT WILL HAPPEN IF I AM HURT?**

*The following statement* ***MUST BE INCLUDED.***

If you are injured because of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.

The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with theprovisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA General Counsel at (202) 461-4900. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

*If research is following a Department of Defense Addendum, include provisions for research-related injury as required by the DOD.*

*For all VHA COVID-19 studies involving a covered countermeasure initiated on/after February 2, 2020, through October 1, 2024 (unless amended). For guidance and to determine if study requires the following liability statement, please see ORD Guidance document dated 8/17/20 located at:* [*https://www.research.va.gov/resources/policies/guidance/Implementation-PREP-Act-COVID19.pdf*](https://www.research.va.gov/resources/policies/guidance/Implementation-PREP-Act-COVID19.pdf)

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 research study.

**WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?**

*The following statement* ***MUST BE INCLUDED.***

You have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. To withdraw your authorization to use and disclose your health information collected as part of the study, you will need to fill out a Revocation of Authorization form. Talk to <PI Name and any authorized member(s) of the study team> if you want to withdraw from the study, including withdrawing your authorization to use and disclose your health information. ***NOTE:*** TheRevocation of Authorization form is located at:<https://www.va.gov/portlandresearch/documents/hrpp/revoke-authorization.pdf>

*For studies involving the collection of human biological specimens, a statement regarding withdrawing consent for use* ***MUST BE INCLUDED.*** *Use language such as the following.*

If in the future you decide you no longer want to participate in this research, you may request to have your <describe the specimens> destroyed by contacting <Name> at <phone number>. If your <describe the human biological specimens> are still identifiable, you may withdraw consent to use them at any time, and <Name> will assure that the specimens that you have given will be destroyed. If you withdraw your consent <and authorization> for such use, you may not be able to continue to participate in the study. You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

*If the PI intends to remove identifiers to keep the subject’s specimen and/or information if the subject no longer wishes to participate, a statement informing subjects* ***MUST BE INCLUDED.*** *Use language such as the following.*

If in the future you decide you no longer want to participate in this research, your <type of human biological specimen and/or information>, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

**Signature**

<PI Name and any other authorized member(s) of the research team> has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

### I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. <PI or, as applicable, Responsible Clinician name> at <insert complete phone number> from <state hours available>, Monday through Friday, and Dr. <Name> at <complete phone number> after <state hours available>. If any medical problems occur in connection with this study, the VA will provide emergency care.

*If the researcher is using human biological specimens, the following statement* ***MUST BE INCLUDED.***

By consenting to participate, I authorize the use of my <describe bodily fluids, substances, or tissues>.

*If the study collects specimens and/or information for optional banking, a statement regarding the banking addendum* ***MUST BE INCLUDED.*** *Use language such as the following.*

If you wish to provide consent to allow your <describe type of human biological specimen and/or information> to be used in research for future studies, you will be asked to signthe banking addendum portion of this consent form.

*If this study includes optional research procedures, not related to optional banking of data/specimens (i.e., included in the Banking Addendum), statement(s) to that effect as well as a place for subjects to initial their consent (and/or refusal)* ***MUST BE INCLUDED.*** *Use language such as the following.*

**PARTICIPANT OPTIONS**

The optional portion<s> of this study <is/are> described in detail above and listed here.  Please read the option<s> and place your initials next to <it if/the option(s) in which> you wish to participate.  You may still participate in the rest of the study, even if you choose not to participate in the optional part.

Example options (modify as appropriate):

\_\_\_\_\_  I give my consent to participate in <the optional blood draws on Day 2 of the study>.

\_\_\_\_\_  I give my consent to participate in the optional <genetic testing for the XYZ gene>.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my <information and/or specimens – describe> as described in this form.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

## *If this study will be enrolling only patients who are capable of consenting for themselves, delete all references to the Subject’s Legally Authorized Representative.*

###### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Subject or Subject’s Legally Authorized Representative

## Signature of Subject or Subject’s Legally Authorized Representative Date Time

## 

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

Relationship to Subject, if Subject’s Legally Authorized Representative

## *If the IRB requires a witness (e.g., if the research involves an invasive procedure or an investigational drug or device), the person obtaining consent may NOT sign as witness. However, the witness may be either a member of the study team or a family member. If no witness is required by the IRB or sponsor, delete all lines referring to a witness.*

* *If the sponsor or IRB requires a* ***witness to the consenting process or to the participant’s*** *signature and if the same person will serve both capacities, a note to that effect should be placed under the witness’s signature line.*
* *If a patient’s signature is an “X,” i.e., the patient is unable to sign his/her name, two adult witnesses unassociated with the study are required.*

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

## Printed Name of Witness to participant’s signature Relationship to Participant/Position Title

\_\_\_\_ Signature of Witness Date Time

## \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Printed Name of Person Obtaining Consent *(This person must be indicated in the protocol by research position title, e.g., PI or research assistant/coordinator, as approved to perform the consent process, and his/her Scope of Work must indicate s/he will perform the informed consent process.)*

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

Signature of Person Obtaining Consent Date Time

* *Retain a copy of each version of submitted form for your regulatory files.*

**Addendum: Banking your <human biological specimens and/or information> for Future Research**

***Use this part of the template only if applicable.***

* *For any repository contribution that is an* ***optional component of study participation*** *(i.e., individuals may still participate in the study if they choose not to contribute), use the addendum as presented.*
* *For any repository contribution that is a* ***required component of study participation****, merge the information from the addendum into the main portion of the ICF instead.*

***NOTE:*** *All repositories storing VA human biological specimens (HBS)**MUST be VA-approved. You may contact the Research Administration Office for assistance in determining whether a repository is VA-approved*. *Please also review the HRPP policy, “IRB Review of Research Repositories” at* [*https://www.va.gov/PortlandResearch/hrpp/index.asp#policies*](https://www.va.gov/PortlandResearch/hrpp/index.asp#policies)*.*

**WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?**

We are <also> asking you to allow your <describe the human biological specimens and/or information, including any identifiers, such as date of study visit or specimen collection> to be stored (“banked”) in a repository located <indicate where – e.g., within the United States>. The repository may then release your <describe the human biological specimens and/or information> for use in future research, which may include research about <indicate the area(s) of research – e.g., a particular disease(s) or disorder(s), or any type of disease, disorder or health condition>.

#### *For future genetic studies:*

Future studies may include genetic research. Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. Future studies will not include sequencing of all or part of your DNA (genomic sequencing).

***OR***

#### Future studies may include genetic research. Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. Future genetic research may also include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

**WHAT ARE THE RISKS?**

*Include the risks of a breach of confidentiality, if identifiable or coded specimens and/or information will be banked. Confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. A breach in confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, etc.) as well as economic harm (e.g., if a social security number were used by someone to gain access to a bank account or credit card through identity theft). Specifically, consider and address the risk of breach of confidentiality or psychological trauma. Suggested language follows:*

Information that <directly identifies you or could be used to identify you> will be banked for the purpose of use in future research. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It could also carry other risks, such as embarrassment or affecting <*list applicable risks:* e.g., ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.>

*The following language is required for human biological specimen repository collection involving possible future genetic research:*

Some members of your family may not want research done on your tissues to understand the genetics or possible inherited disorders of you and your family. This may cause conflict with your family members and could affect your decision or the decisions of family members to have children. You may want to hold a discussion with your family members before deciding to participate in this study and signing this consent form.

*For future research using these samples or data, genetic data that may be shared in a public database (e.g. per the NIH Genomic Data Sharing Policy), state [modify as applicable]:*Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

The Genetic Information Nondiscrimination Act (GINA), a federal law, generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more employees to discriminate against you based on your genetic information.

* 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.
* However, there is a serious risk, if there is a loss of confidentiality and certain genetic information reaches your current or future life, disability or long-term care insurance carrier, your employer (if s/he employs fewer than 15 employees), or others, that you or members of your family may experience some type of discrimination resulting in (1) **loss of life insurance, disability insurance, or long-term care insurance coverage** **and/or** (2) **loss of job**. All researchers associated with this study and the repository will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists despite every reasonable effort. If you have any questions, please ask <PI>, who can be reached at <phone number>.
* The VAPORHCS also abides by the Oregon Genetic Privacy law (ORS 192.531 through ORS 192.549) and its requirements concerning confidentiality and the legal remedies provided by that law for breach of its requirements. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the VA Regional Counsel office at (503) 412-4580.

WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY?

*If the study collects/banks blood/tissue, even if identifiers are removed, the following statement MUST BE INCLUDED.*

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to an individual, the federal government or a private entity. There are no plans to provide financial compensation to you should this occur. However, should the VA ever provide your samples for research or commercial use, it will do so in such a way asto protect yourprivacy and confidentiality as stated in the CONFIDENTIALITY section of this document.

**HOW LONG WILL YOU KEEP MY INFORMATION?**

Your <describe the human biological specimens and/or information> will be stored <for (duration) or until (date)> and will then be destroyed.

***OR***

Your <describe the human biological specimens and/or information> will be stored indefinitely.

**WILL I BE TOLD ABOUT ANY FUTURE RESEARCH RESULTS?**

If you give your permission for your <describe the human biological specimens and/or information> to be used in future studies, the results of those studies involving the use of your specimens will not be made available to you because <reasons>.

***OR***

If you give your permission for your <describe the human biological specimens and/or information > to be used in future studies, we will contact you with results of those studies because <reasons>.

**CAN I WITHDRAW MY PERMISSION TO USE MY *<SPECIMENS AND/OR INFORMATION>?***

***Modify as appropriate to align with study protocol.***

If your <describe the human biological specimens and/or information> are still identifiable, you may withdraw consent to use them at any time. This includes the right to withdraw your authorization to use and disclose your health information. To withdraw your authorization to use and disclose your health information, you will need to fill out a Revocation of Authorization form. Talk to <PI Name and any authorized member(s) of the study team> if you want to withdraw from the study, including withdrawing your authorization to use and disclose your health information. ***NOTE:*** TheRevocation of Authorization form is located at:<https://www.va.gov/portlandresearch/documents/hrpp/revoke-authorization.pdf>

*For identifiable (by the repository, either directly or using a key code) human biological specimens and/or information, use language such as the following.*

If you agree, your <describe the human biological specimens and/or information> may be used in future research as described below. The <specimens and/or information> in the repository will be <labeled with or linkable to> <specify identifiers - e.g., your name, medical record number, Social Security number, etc.>. This is <justify why it is necessary to for the repository to have identifiable specimens and/or information>.

Other researchers who receive your <specimens and/or information> from the repository for future research will <not> be able to link the <specimens and/or information> to you. Your <specimens and/or information> will not be given to product manufacturers, such as drug companies.

***OR***

*For coded (i.e., linkable by any members of the contributing study team, including those also on the repository staff) human biological specimens and/or information, use language such as the following.*

If you agree, your <describe the human biological specimens and/or information> may be used in future research as described below. A code number that doesn’t contain any personal identifiers (such as your initials or date of birth) will be assigned to your <describe the human biological specimens and/or information>. Only personnel working on this study will be authorized to link the code number to you. <However, some of these personnel also work for the repository.> Other researchers who may receive your < specimens and/or information> for future studies will be given only the code number, and will not be given any other information allowing them to link back to you or your family.

***OR***

*For de-identified human biological specimens and/or information, use language such as the following.*

If you agree, your <describe the human biological specimens and/or information> may be stored and used in future research. All personal identifiers (such as initials and date of birth) and links to those identifiers will be removed before the <specimens and/or information> <is/are> given to the repository. Once that happens, the study personnel, repository personnel and other researchers will not have information to link the <specimens and/or information> back to you.

*For* ***all*** *human biological specimens and/or information, use language such as the following.* ***NOTE:*** *If you wish to allow participants different option(s) to which they may agree, clearly identify the options and provide line(s) for subjects to place their initials next to the option(s) they agree to.*

I agree to the following regarding future uses <(including genetic research)> of my <identifiable, coded or de-identified, as per the sections above> <describe the human biological specimens and/or information>:

* Only research about <specify health care issue(s), disease(s) and/or disorder(s)>

***OR***

* Research about any type of health care issue, disease or disorder ***AND***
* Only researchers from this study

***OR***

* Any <VA> researchers ***AND***
* Only after contacting me in the future for additional consent

***OR***

* Without contacting me in the future for additional consent

**Signature**

<PI Name and any authorized member(s) of the study team> has explained the banking of my <describe the human biological specimens and/or information, including any identifiers> for future research to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the banking.

### I have been told that I may refuse permission for banking of my <describe the human biological specimens and/or information, including any identifiers> for future research and that refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call <PI> at <insert complete phone number>

*If the researcher is using human biological specimens, the following statement* ***MUST BE INCLUDED.***

By consenting to participate, I authorize the use of my <describe bodily fluids, substances, or tissues>.

My signature below indicates that I have read, or had read to me, all of the above information about the banking of my <describe the human biological specimens and/or information>, and that my rights as a research subject have been explained to me.

I voluntarily consent to allow the <describe the human biological specimens or information> from this study to be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

## *If this study will enroll only patients capable of consenting for themselves, delete all references to the Subject’s Legally Authorized Representative.*

###### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Subject or Subject’s Legally Authorized Representative

## Signature of Subject or Subject’s Legally Authorized Representative Date

Relationship to Subject if Subject’s Legally Authorized Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## *If the IRB requires a witness (e.g., if the research involves an invasive procedure or an investigational drug or device), the person obtaining consent may NOT sign as witness. However, the witness may be either a member of the study team or a family member. If no witness is required by the IRB or sponsor, delete all lines referring to a witness.*

* *If the sponsor or IRB requires a witness to the consenting process or to the participant’s signature and if the same person will serve both capacities, a note to that effect should be placed under the witness’s signature line.*
* *If a patient’s signature is an “X,” i.e., the patient is unable to sign his/her name, two adult witnesses unassociated with the study are required.*

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

## Printed Name of Witness to participant’s signature Relationship to Participant/Position Title

Signature of Witness Date

## 

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

## Printed Name of Person Obtaining Consent *(This person must be indicated in the protocol by research position title, e.g., PI or research assistant/coordinator, as approved to perform the consent process and his/her Scope of Work must indicate s/he will perform the informed consent process.)*

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

Signature of Person Obtaining Consent Date Time

* *Retain a copy of each version of submitted form for your regulatory files.*

**Addendum: Banking your Contact Information for Future Research**

***Use this part of the template only if applicable.***

* *For any repository contribution that is an* ***optional component of study participation*** *(i.e., individuals may still participate in the study if they choose not to contribute), use the addendum as presented.*
* *For any repository contribution that is a* ***required component of study participation****, merge the information from the addendum into the main portion of the ICF instead.*

***NOTE:*** *All repositories storing VA human biological specimens (HBS)**MUST be VA-approved. You may contact the Research Administration Office for assistance in determining whether a repository is VA-approved*. *Please also review the HRPP policy, “IRB Review of Research Repositories” at* [*https://www.va.gov/PortlandResearch/hrpp/index.asp#policies*](https://www.va.gov/PortlandResearch/hrpp/index.asp#policies)*.*

**WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?**

We are <also> asking you to allow your contact information (including <specify identifiers> <and data – specify>) to be stored (“banked”) in a repository located at VA Portland Health Care System (VAPORHCS). By signing this form below, you agree to allow your contact information <and data> listed above to be made available to researchers at the VAPORHCS for the purpose of contacting you about future research studies.

**WHAT ARE THE RISKS?**

Information that identifies you will be banked. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It could also carry other risks, such as embarrassment or affecting <list applicable risks – e.g., ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community>.

**HOW LONG WILL YOU KEEP MY INFORMATION?**

Your research data will be stored <indefinitely or, if data will be banked for a limited duration, please indicate>.

**CAN I WITHDRAW MY PERMISSION TO USE MY CONTACT INFORMATION <AND DATA>?**

***Modify as appropriate to align with study protocol.***

If your <describe the human biological specimens and/or information> are still identifiable, you may withdraw consent to use them at any time. This includes the right to withdraw your authorization to use and disclose your health information. To withdraw your authorization to use and disclose your health information, you will need to fill out a Revocation of Authorization form. Talk to <PI Name and any authorized member(s) of the study team> if you want to withdraw from the study, including withdrawing your authorization to use and disclose your health information. ***NOTE:*** TheRevocation of Authorization form is located at:<https://www.va.gov/portlandresearch/documents/hrpp/revoke-authorization.pdf>

**HOW WILL MY CONTACT INFORMATION <AND DATA> BE USED FOR FUTURE RESEARCH?**

If you agree, your <list identifiers and any data to be banked> may be used by VAPORHCS researchers to contact you regarding future research studies.

I agree to the following future uses of my contact information:

* Contacting me <in person when I come to the VA, by letter, by phone> ***AND***
* Only research about <specify health care issue(s), disease(s) and/or disorder(s)>

***OR***

* Research about any type of health care issue, disease or disorder ***AND***
* Only researchers from this study

***OR***

* Any VA researchers

**Signature**

< PI Name and any authorized member(s) of the study team> has explained the banking of my contact information <and data - describe> for future research to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the banking.

I have been told that I may refuse permission for banking of my contact information <and data – describe> for future research and that refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call <PI> at <insert complete phone number>.

My signature below indicates that I have read, or had read to me, all of the above information about the banking of contact information <and data – describe>, and my rights as a research subject have been explained to me.

I voluntarily authorize my contact information <and data – describe> be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

## *If this study will enroll only patients capable of consenting for themselves, delete all references to the Subject’s Legally Authorized Representative.*

###### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Subject or Subject’s Legally Authorized Representative

## Signature of Subject or Subject’s Legally Authorized Representative Date

Relationship to Subject, if Subject’s Legally Authorized Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## *If the IRB requires a witness (e.g., if the research involves an invasive procedure or an investigational drug or device), the person obtaining consent may NOT sign as witness. However, the witness may be either a member of the study team or a family member. If no witness is required by the IRB or sponsor, delete all lines referring to a witness.*

* *If the sponsor or IRB requires a witness to the consenting process or to the participant’s signature and if the same person will serve both capacities, a note to that effect should be placed under the witness’s signature line.*
* *If a patient’s signature is an “X,” i.e., the patient is unable to sign his/her name, two adult witnesses unassociated with the study are required.*

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

## Printed Name of Witness to participant’s signature Relationship to Participant/Position Title

Signature of Witness Date

## 

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

## Printed Name of Person Obtaining Consent *(This person must be indicated in the protocol by research position title, e.g., PI or research assistant/coordinator, as approved to perform the consent process and his/her Scope of Work must indicate s/he will perform the informed consent process.)*

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

Signature of Person Obtaining Consent Date Time

* *Retain a copy of each version of submitted form for your regulatory files.*