**DELETE THIS HIGHLIGHTED SECTION PRIOR TO SUBMISSION**

**Instructions**: This VA informed consent form template should be used for human research studies reviewed by the University of Maryland, Baltimore IRB that include VAMHCS as a site of conduct. Please include all applicable sections and required language, adding specified study information, as instructed in blue, unless otherwise indicated. The document should be written so that a person with a seventh grade reading level could understand. Using words understandable to a non-technical, non-medical audience is recommended.

**Key**

Black Font = VHA-required language, must be included verbatim

Blue Font = VAMHCS Research Office instructions and suggestions

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**IRB Study Number:** [UMB protocol number only]

**Sponsor:** [Delete if not applicable]

**INTRODUCTION**

You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS) and [include other sites if applicable]. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

[Include the following sentence only when applicable] If an individual is consenting for someone else (i.e. a child or an adult unable to provide consent themselves), then the word “you” in this form means that person for whom you, as the Legally Authorized Representative, are providing consent.

**CONCISE SUMMARY**

* All key information must be briefly summarized at the beginning of the informed consent document (in a brief paragraph or two, consuming no more than half a page). Examples of concise summaries can be found in the University of Maryland, Institutional Review Board website:<https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/>
* Consider the following when constructing the concise summary with key information:
	+ The prospective research participant or legally authorized representative must be provided with information “that a reasonable person would want to have in order to make an informed decision,” as well as an opportunity to discuss such information.
	+ The informed consent must begin with a concise and focused presentation of the key information most likely to assist in comprehension of why one may or may not want to participate in the study.
	+ The focused and concise summary should include:
		- Statement that the project is research, and that participation is voluntary
		- Summary of purpose, duration, procedures, key risks, discomforts, and benefits
		- Other key information as appropriate, such as summary of cost and payment information or alternatives to participation in the research (especially for treatment studies).
		- Rather than a list of isolated facts, the goal is to help process the information given to make it easier for a subject or legally authorized representative to make an informed decision.

**RESEARCH DETAILS**

* The below sections should elaborate on the information that was included in the concise summary above.

**PURPOSE OF THE STUDY**

* This section should include required components of informed consent elements.
* If an investigational drug or device is being used and an IND/IDE has been obtained, please describe and state that the FDA is allowing the use of this in the study.
* Please state if a placebo is being used.
* Explain how/why the potential participant qualifies for the study and inform him/her why he/she is being asked to participate in the study.
* Do not include inclusion/exclusion criteria in consent form unless the criteria are directly relevant to the subject's decision making, e.g., safety issues, excluded medications, changes in behavior such as alcohol use.
* State the number of participants at this site and in total if this is a multi-center study.
* \*\*\***If this is a “collaborative study” with the University of Maryland or other collaborators, state that this is a “collaborative” study that will combine VA research activities and VA data with [include other sites if applicable] research activities and [list other sites if applicable] data.**

**STUDY PROCEDURES**

* Briefly explain in lay terms the study design, as well as the procedures the participant will undergo if he/she agrees to join the study.
* Explain how treatment groups will be assigned (if applicable).
* If randomization will determine treatment assignment, explain it in readily understandable terms. It is suggested that randomization means that treatment will be determined by chance like drawing a card, drawing a number, or flipping a coin. For example: “*The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment.”*
* For double-blinded studies add: *“Neither you nor the study doctor will know which treatment you are getting.”*
* For single-blinded studies add: *“You will not be told which treatment you are getting, however your study doctor will know.”*
* Specify:
	+ The number of required hospital visits
	+ The number of required clinic visits
	+ Inpatient or outpatient actual time commitment involved in participation
* State the expected duration of participant’s participation.
* Describe each procedure/visit in a brief paragraph using simple language that a person with a seventh-grade education could understand
* Specify where each procedure/visit will take place (VAMHCS-room-suite #, UMB-room-suite #, other institutions). It may be advisable to include a “Study Activities Chart” depicting the location of the activities in this ICF.
* If a separate UM ICF will be signed for UM portions of the study, explain this to the participant and summarize the UM portion of the study. (See example LOCATION OF STUDY PROCEDURES section.)
* Clearly state the amount of blood to be drawn at each visit and the total amount to be drawn over the course of the study (in household measures, i.e. teaspoons).
* Clarify what will be done to the participant solely for research purposes and/or what is experimental in the project (including a detailed description of the investigational agent or device, if applicable). Differentiate “research” from “usual care.”
* If the study procedures are long and complex and include several steps, use a bulleted format and short paragraphs. It is recommended that a flow chart be included in the consent form to enhance the participant’s ability to understand the procedures.

**WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?**

If you take part in this research, you will be responsible to: [describe any responsibilities of the subject in a bulleted list or paragraph form].

**POTENTIAL RISKS/DISCOMFORTS**

* Describe any foreseeable risks or discomforts to the participant that are related only to the research in clear simple terms.
* Risks should be stated by the severity and likelihood, or they should be compared with natural risks that are understood by most patients. Use categories such as likely, less likely, unlikely, and/or rare.
* Along with physical risks, be sure to consider social, psychological, legal, and economic risks.
* All consent forms should list the risk of the potential for the loss/breach of confidentiality.
* There may be risks to the participant which are currently unforeseeable unless the risk profile of all research-related interventions is well known, and the research involves no investigational drugs or devices. If there are unforeseeable risks, please include the following statement: *“There may be risks in this study which are not yet known.”*
* In addition, please state how all risks will be minimized. For example, state, if applicable: *“Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet”* or *“Electronic data will be password-protected.”*

If applicable:

* Include pregnancy and/or male and female fertility risks to the adult.
* If the research involves pregnant women or women of child-bearing potential and involves an investigational product or procedures whose risk profile in pregnancy is not well known, add: “*If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown.”*
* For research that involves risks to an embryo or fetus add: “*The procedures involved in this research may harm a pregnancy or unborn child in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You should not become pregnant or father a baby while in this research study.”*
* Include any risks to a nursing infant if applicable.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY? (Delete this section if not applicable)**

* State that participants will be informed of new findings that may affect the participant’s willingness to continue participation. This section may be omitted if new information could not reasonably be used to alter participation (e.g., one-time interventions that are no greater than minimal risk).
* \*\*\*Include a statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions

**MEDICAL TREATMENT AND COMPENSATION FOR INJURY**

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: [List local site contacts. For example:]

DURING THE DAY:

Dr./Mr./Ms. at and

AFTER HOURS: (For greater than minimal risk studies, if required by the IRB, or if the PI feels it should be included)

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

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

**POTENTIAL BENEFITS**

* If the participant will not benefit from participation, clearly state: *“You will not benefit directly from your participation in this study.”*
* If there is the potential for the participant to benefit, state: *“You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study.”* State the potential personal or societal benefits of participation.
* Do not overstate direct benefits to participants when it is not realistic to expect benefits.
* If applicable, state possible general benefits for science or other patients with similar diseases, or for the population at large (if applicable). However, do not state such benefits if the person who will be consenting is a surrogate for the research subject, and should not be considering those benefits.
* Receiving healthcare, payment, or other consideration for participation in a research study is not considered a benefit.

**COSTS TO PARTICIPANTS**

* Include the following statement that a participant will not be required to pay for care received as a participant in a VA research project except as follows: “*You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.”*
* Detail any additional costs to the participants which may result as a consequence of their participation in the study, for example, co-pays, deductibles, parking fees, etc.
* If there are no costs to the participant, state: *“It will not cost you anything to take part in this study.”*
* For studies that involve a treatment intervention, this section should clearly state whether or not participants will be responsible for any costs of treatments, drugs, or devices that are conducted solely for the purpose of the research, i.e. costs of tests and visits that would not occur if the participant was not in a research study but instead was receiving the standard of care. If sponsor will pay the costs if the participant’s insurance does not, please include a statement.
* If you do not anticipate any financial support, and the project involves clinical procedures conducted primarily for research purposes, provide an explanation of the expected source of payment for these procedures (specifically state who will pay or whether the participant will be responsible for payment). **NOTE:** VA participants cannot be responsible for payment. Ensure that the language does not conflict with the CRADA or another contract.The IRB seeks reassurance that participants will not have undisclosed financial risks due to participation in the research study.

**PAYMENT/REIMBURSEMENT TO PARTICIPANTS**

* Outline remuneration amount or other compensation and procedure, for example, check, VA voucher, gift certificate, transportation.
* If no compensation is to be offered, then state that participants will not be paid.
* If participants will be reimbursed for parking and/or travel, please include that here.
* If this study includes compensation to participants for their participation in the study which is in excess of $600 in a calendar year, include a statement that informs participants that they will be responsible to report this income to the IRS.
* State who will be disbursing the payments. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. This information and the fact that the SSN of the subject will be used for this purpose must be included in the informed consent form.
* **NOTE:** VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care. Any payment offered should be **commensurate with the time** and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses

**ALTERNATIVES TO PARTICIPATION**

* Explain realistic alternatives to participation; specifically, state what treatment is available or that might be advantageous if participant declines to participate. Include for example, approved standard of care, other research studies, palliative care, or no treatment.
* If the research does not involve a treatment intervention, state: “*This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your**healthcare at the VA Maryland Health Care System (VAMHCS)**will not be affected.”*

**RIGHT TO WITHDRAW**

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

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or stopping your participation in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator [Insert Name of VA PI] at 410-605-7000 extension [Insert VA extension].

* Please state that either:
	+ There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

 OR

* The consequences of a participant's decision to withdraw from the research. If the latter applies to this study, then please also state the procedures for orderly termination of participation by the participant. State that a written withdrawal is requested/required and to whom it should be sent.
* If applicable, please add the following:
* “*You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.*”
* If the study includes students, staff or faculty, a statement must be included to state: “*If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study*.”
* For clinical trials, include:
	+ *“If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.”* [Note: The consent document cannot give the subject the option of having data removed.] “*If you agree, this data will be handled the same as research data.*” [Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]

**Can I be removed from the research? (Delete this section if not applicable)**

* This section may be omitted if there is only a one-time intervention or there are no circumstances in which the investigator would terminate the participation of an individual participant.
* Include the following:

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [add reasons why the subject may be withdrawn, if appropriate. For example: failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer in your best interest.]The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

**CONFIDENTIALITY AND ACCESS TO RECORDS**

* Explain whether or not the study will involve confidential information. If it does, briefly indicate:
	+ Who will have access to the information
	+ Whether or not it will be coded
	+ What measures investigators will use to ensure the information is maintained in a confidential manner
	+ Whether or not the participant’s name or other identifier will be used
	+ How audio and video tapes will be stored and destroyed at the end of the study
* If the study procedures have any implication on the patient’s care, the study team is required to put any details about the subject’s participation that are relevant to their care providers in the patient’s medical record. Therefore, for all studies that involve a medical intervention, you must include the following statement: “*We will include information about your study participation in your medical record.”*
* For all studies that involve the collection of identifiable private information or identifiable specimens, include a statement on whether specimens if subsequently de-identified will be used for future research or not.
* If information requiring a Confidentiality Certificate is to be involved (i.e. illegal criminal behavior, drug use, physical abuse, sexually sensitive material, and HIV status), state the protections afforded by the Certificate (please see below). In the absence of a Certificate, state that the confidentiality of data will be maintained to the fullest extent permitted by law.
* Inform participants that study records will be considered confidential, and (if appropriate), that the participant’s name will not be used in reports or publications.
* Include the following:

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the University of Maryland IRB, VA Office of Research and Development, VA Office of Research Oversight, VA Office of Inspector General, Office of Human Research Protections, VAMHCS Office of Research Compliance, Food and Drug Administration, when the research if FDA-regulated, the sponsor, contract research organization, sponsor’s agent and other collaborating

institutions.]

* For clinical trials, include: “The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.”
* If HIV/Hepatitis/TB testing will be done, please add a statement that a positive result will be reported, as required under State law. *Note: “There are many other reportable conditions. To see a list go to:* [*https://health.maryland.gov/phpa/Pages/what*](https://health.maryland.gov/phpa/Pages/what)*-to-report.aspx.”*
* Inform if the participant will receive a report of the aggregate results or any results specific to the participant. **The following statement is required by the VAMHCS:**

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The “records control schedule” is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS “HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research”. However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

* For FDA-regulated non-Phase I controlled trials, add:
	+ “*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.”*
* **For ALL NIH-funded research and any other research with a Certificate of Confidentiality, include:** *“The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:*
1. *There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);*
2. *You have consented to the disclosure, including for your medical treatment;*
3. *The research information is used for other scientific research, as allowed by federal regulations protecting research subjects;*
4. *For the purpose of auditing or program evaluation by the government or funding agency; or*
5. *[If FDA-regulated] if required by the federal Food and Drug Administration (FDA).*

*You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.*

*Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.”*

**DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED? (Delete this section if not applicable)**

* Include a statement whether the research might include whole genome sequencing.
* Describe in this section possible limits to individual confidentiality based on the technologies involved in the research. Clarify when and under what conditions research results of genetic testing will be conveyed to the participant, the participant’s family, or the participant’s physician.
* Include the following statement verbatim, if applicable:

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

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

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

**WILL ANY OF MY DATA BE STORED FOR FUTURE USE BEYOND THE PURPOSES OF THE CURRENT STUDY? (Delete this section if not applicable)**

* If any of the participant’s data are going to be retained after the study for future research, clearly state that and provide the following information to the participant:
	+ Where will the data be stored
	+ Who will have access to the data
	+ Purpose of storage for future use
	+ How will the data be secured
	+ Procedures to protect confidentiality
	+ Will the data be identifiable

We request your permission to store your data indefinitely for future research purposes, with high attention to protecting your privacy and adequate security measures. Please read each sentence below, think about your choice, and initial next to “YES” or “NO”. No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

May the [site] or its research partners in this study retain your data after the end of the study for use in future research?

\_\_\_\_\_**YES,** my data may be saved for future research.

\_\_\_\_\_ **NO,** my data must be destroyed at the end of this research study.

**\*\*\*\*\*IF DATA STORAGE FOR FUTURE USE IS AN OPTIONAL COMPONENT OF THE STUDY (AS OUTLINED ABOVE), A COMBINED CONSENT/HIPAA CANNOT BE USED. IN CASE OF OPTIONAL DATA STORAGE, SIMPLY DELETE THE HIPAA LANGUAGE AT THE END OF THIS FORM AND INSTEAD USE A SEPARATE HIPAA DOCUMENT (FORM 10-0493).**

**WILL ANY OF MY SPECIMENS (BLOOD/TISSUE/URINE) BE BANKED FOR FUTURE USE BEYOND THE PURPOSES OF THE CURRENT STUDY?** **(Delete this section if not applicable)**

* For studies involving banking of specimens, participants should be informed of the following:
	+ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and then could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative

 ***OR***

* + A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be distributed for future research studies
* If any of the participant’s samples are going to be retained after the study for future research, clearly state that and provide the following information to the participant:
	+ Where will the samples be stored
	+ Who will have access to the samples
	+ Purpose of storage for future use
	+ How will the samples be secured
	+ Procedures to protect confidentiality
* A separate consent form will also be required for the collection of DNA for the sole purpose of adding the specimen to the CSP VA Genomic Medicine Program Biorepository or if a specimen will also be used for the Million Veteran Program (MVP).
* Include the following:

We request your permission to store your donated samples for future research purposes indefinitely, with high attention to protecting your privacy and adequate security measures. Please read each sentence below, think about your choice, and initial next to “YES” or “NO”. No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

May the [site] or its research partners in this study retain your [describe specimen (e.g., tissue, blood, urine, body fluid)] specimen(s) after the end of the study for use in future research?

\_\_\_\_\_**YES,** my specimen(s) may be saved for future research.

\_\_\_\_\_**NO,** my specimen(s) must be destroyed at the end of this research study.

If yes, may the [site] or its research partners in this study keep your name and other identifying information with your specimen(s)?

\_\_\_\_\_ **YES,** my personal identifiers and medical information can be kept with my specimen(s). All information will be kept secure and confidential.

\_\_\_\_\_ **NO,** my name and identifiers must be removed from my specimen(s). My specimen(s) cannot be linked back to me.

If you give consent for the specimen(s) to be used in future research by the VAMHCS or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your unused specimen destroyed. You need to notify the investigator in writing of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

**\*\*\*\*\*IF SPECIMEN BANKING IS AN OPTIONAL COMPONENT OF THE STUDY (AS OUTLINED ABOVE), A COMBINED CONSENT/HIPAA CANNOT BE USED. IN CASE OF OPTIONAL BANKING, SIMPLY DELETE THE HIPAA LANGUAGE AT THE END OF THIS FORM AND INSTEAD USE A SEPARATE HIPAA DOCUMENT (FORM 10-0493).**

**WILL I BE RECONTACTED AFTER THE STUDY?**

* If the subject is going to be recontacted in the future about participating in future research or for any other reason, this must be clearly stated in this section. Describe the circumstances under which the participant would be re-contacted whether within the VA or outside the VA.
* Provide the following option for re-contact:

Please read each sentence below and initial next to “YES” or “NO”. No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

May the [site] or its research partners in this study contact you after this research study is over to [provide reason]?

\_\_\_\_\_**YES,** I consent to be re-contacted.

\_\_\_\_\_**NO,** I do not want to be re-contacted.

**WHO COULD PROFIT FROM THE STUDY RESULTS? (Delete this section if not applicable)**

* Describe any payments that are being made to investigators that could be construed as a potential conflict of interest. If a conflict of interest cannot be eliminated after the review by the IRB, the IRB may require that this section be included.
* Include a statement whether specimens may be used for commercial profit and if subjects will share in the profit.
* If a possible commercial product will be developed as part of this research, explain that the participant will not profit from any products or tests that might result based on research with their specimens.

**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT**

**(HIPAA)**

* Delete this HIPAA section if your study contains elements of optional banking of biospecimens or data or if a legally authorized representative will consent and authorize on behalf of the research participant. You would need a separate VA Form 10-0493 in those case.
* Please ensure that you incorporate the verbatim HIPAA elements printed below in black, if your study is eligible to use the combined consent and HIPAA format.

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

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

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the {MODIFY AS APPROPRIATE…Include as applicable - Institutional Review Board (IRB), VAMHCS Office of Research Compliance (ORC), Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), VA Office of Research Oversight (ORO), Government Accountability (GAO), VA Cooperative Studies Program (CSPCC); CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC’s Human Research Committee (HRC)]; {YOU CAN ALSO ADD ENTITIES SUCH AS SPONSOR, CONTRACTORS, AFFILIATES AS APPROPRIATE…whoever might need to see your study data for either regulatory or other purposes};

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

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

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

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

**CONTACTS AND AGREEMENT**

**WHO ELSE CAN I CONTACT ABOUT THIS STUDY?**

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB-approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

**University of Maryland Baltimore**
**Institutional Review Board**

**Human Research Protections Office**
620 W. Lexington Street, Second Floor
Baltimore, MD 21201

410-706-5037

You may also contact the VAMHCS Research Protections Officer (RPO)**.**

VAMHCS Research Protections OfficerBaltimore VA Medical Center10 North Greene Street, Mail Stop 151
Baltimore, MD 21201

443-421-5602

The VAMHCSRPOmay contact you in the future to ask you about your experiences with this research study.

[Insert a page break. The signature page should be a separate page that contains all the signatures and the signing statement.]

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study [INSERT VERBATIM IF THIS FORM IS COMBINED WITH HIPAA AUTHORIZATION: and authorize the use and disclosure of your health information for this study]. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Person Obtaining Consent (Print) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Consenter’s Signature |  \_\_\_\_\_\_\_\_\_\_\_\_ Date |

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

*IMPORTANT: The below signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block in place of the participant’s signature block if it has been explained in the new study application (subject to approval by the IRB) that these types of populations are going to be used in the study). Delete this section if you do not plan to enroll participants using an LAR.* ***Please delete the HIPAA section in this template if an LAR will be used as you must use the VA Form 10-0493.***

|  |
| --- |
| **The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of Legally Authorized Representative (Print) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Legally Authorized Representative | \_\_\_\_\_\_\_\_\_\_Date |
| **Indicate below your authority to act as the participant’s legally authorized representative:**[ ]  Spouse[ ]  Parent[ ]  Adult Child (18 years of age or over) for his or her parent [ ]  Adult Sibling (18 years of age or over)[ ]  Grandparent[ ]  Adult Grandchild[ ]  Guardian appointed to make medical decisions for individuals who are incapacitated[ ]  Other per local or state law Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |