**What is this research about?**

*Briefly describe the purpose of the study and why it’s being conducted – what you hope to learn from the study.*

**What is expected of me? (Procedures)**

*Briefly describe the study procedures, including the duration of direct study participation. If photo/video/audio recording add: You will be asked to (describe video/audio recording, how they will be used for the research, whether they will be disclosed outside VA, and what will become of recordings after use, e.g., shown at scientific meetings; describe the final disposition of the recordings. If disclosed to an outside entity, this must be stated in the HIPAA authorization).*

**What are the possible risks or discomforts?**

*Describe the reasonably foreseeable risks of study participation. If there are no risks, state such.*

**Will I benefit from the study?**

*Describe the benefits to the participant of study participation. If there are no direct benefits, you can state such.*

**What are my alternatives to being in this study?**

*If there are alternative treatments to this study that the participant can take part, describe them. If the study is not a treatment study, you can state there are no alternatives to the study or you can request an alternation of consent from the IRB to leave this required consent form element out.*

**Will I get paid?**

*Describe payment if any, including if the payment will be prorated based on study visits or procedures. If there is no payment, state such.*

*\*If paying participants, add the following* You may need to provide your social security number to receive payment.

**Will I have to pay anything?**

**Note:** Veterans who participant in VA research cannot be required to pay for care received during the study. Some veterans may be required to pay co-payments for routine medical care.

If this is a study that involves routine medical care, include the following**:**

\*There will be no costs to you for any of the treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

\*If the study does not involve routine medical care, **include the following:** You will not have to pay anything to be in this study.

**Do I have to be in this study?**

*Include a statement saying participation is voluntary and that a decision not to participate will not result in any penalty or loss of benefits the participant may be entitled.*

**Can I change my mind later and stop being in this study?**

*State that the participant can withdraw from the study at any time without penalty or loss of benefits they may be entitled.*

**Will my information be protected from the public?**

*Include the following information on how you will keep the study information confidential and that federal agencies may have access to the records.*

If this study collects identifiable private information and/or identifiable specimens include one of the two following statements:

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

OR
Your information and/or specimens will not be used or distributed for future research studies even if all identifying information is removed.

\*The purpose of the data collected for this project is for scientific research only and there will be no attempt to identify directly or indirectly any subjects in the research data. We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Information about you participating in this research study may be added to your VA Medical Records.

\*Include the following language if this study is NIH funded:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[THE AGENCY]* which is funding this project 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 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.

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research information in the medical record]*.

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

*The written VA HIPAA Authorization may not be combined with the informed consent form when the project involves:*

* *Use of data or specimens for banking or further analysis (future use projects).*
* *The study subject population is expected to include subjects with legally authorized representatives/legal guardians and/or personal representatives.*

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.

**How will my health information be used in the study?**

*Describe how the health information will be used in the study.*

**What Personal Health Information Will Be Used or Shared?**

The following health information, *linked to you by [insert the identifiers that will be used: e.g., your name, SSN, date of birth]* will be used for this research:

*Individually list the medical information you will use or disclose in this study. Information included should be limited to the least amount of information needed to accomplish the purpose of the research. Potential categories of information include:*

* Medical history and physical examination information
* Progress notes
* Laboratory Test Results on blood, tissue, urine, saliva
* HIV (testing or infection) records
* Sickle cell anemia information
* Operative reports
* X-ray and MR scans
* Discharge summary
* Survey/Questionnaire responses
* Mental health (not psychotherapy) notes
* Psychological test results
* Drug abuse Information
* Alcoholism or alcohol use information
* Photographs, videotapes, other images
* Billing records
* *Other* (describe information)

**Who May Use or Share Your Health Information?**

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

* The Principal Investigator (Insert Name of VA Principal Investigator)and members of the VA research team.
* Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.
* The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

**Who May Receive and Use Your Health Information?**

The investigators may share your health information with the following individuals as part of this research study.

*List all other collaborating investigators who will receive VA identifiable data. Note: If this study is being done by investigators at both VA Palo Alto and Stanford University and VA identifiable data will be shared with your Stanford colleagues, include the following:*

* Stanford University collaborating investigators and research staff.

*If the study is sponsored, list the study sponsor (i.e., industry sponsor or NIH), including any CRO, outside lab or data monitoring board that will receive participant information.*

*If study funding is administered by PAVIR, include:*

* The Palo Alto Veterans Institute for Research (PAVIR), who administers the funding for this project, and any agents or outside entities hired by PAVIR to assist them in carrying out their responsibilities

*The following two entities must be included:*

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* Other outside individuals or entities hired by the VA Palo Alto Health Care System to do certain work in support of the VA Health Care System

*If the study involves a drug or device, include:*

* The Food and Drug Administration

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

**Do I have to sign this form?**

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study [or receive any research-related treatment *(add if a treatment study*)].

**If I sign now, can I decide later not to continue in the study?**

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give your written request to the investigator or send it by mail to: [insert VA Principal Investigator and address]

**Does My Permission for the use my Personal Health Information Expire?**

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed or on \_\_\_\_\_\_ [insert date].

*HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.*

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

Signature of Participant Date

***Note:*** *If the participant lacks the capacity to give consent, the HIPAA authorization must be obtained from the participants “Personal Representative” (defined as a person with durable power of attorney for health care for the participant or that is the participant’s legal guardian or court appointed conservator)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_
Signature of Personal Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Description of Representative's Authority to Act for Participant

**What happens if I think I’ve been hurt by being in this study?**

If you are injured as a direct result of being in this study, medical treatment will be available.  If you are eligible for veteran’s benefits, the cost of such treatment will be covered by the VA.  If not, the cost of such treatments may still be covered by the VA depending on a number of factors.  In most circumstances, the treatment must be provided in a VA medical facility.  No other form of compensation for injuries is available.  However, by signing this form you have not released the VA from liability for negligence.   You should contact the Principal Investigator if you feel you have been hurt by being a part of this study.

**Who can I talk to about a Research Related Injury?**

\*If the project is unfunded or federally funded, include the following verbatim:

If you are injured as a direct result of being in this study, medical treatment will be available.  If you are eligible for veteran’s benefits, the cost of such treatment will be

covered by the VA.  If not, the cost of such treatments may still be covered by the VA depending on a number of factors.  In most circumstances, the treatment must be

provided in a VA medical facility.  No other form of compensation for injuries is available.  However, by signing this form you have not released the VA from liability for negligence.   You should contact the Principal Investigator if you feel you have been hurt by being a part of this study.

If this study uses a drug, device or vaccine designed to treat, diagnose, cure or mitigate COVID-19, the language regarding the PREP Act below must be included in the consent form:

**\*** 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.

**Who can I talk to if I have questions about the research, problems related to the study or if I think I’ve been hurt by being a part of the study?**

*Include the following contact information:*

If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, (name and phone number of the investigator). You should also contact them at any time if you feel you have been hurt by being a part of this study.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at (650)-723-5244 or toll free at 1-866-680-2906.  You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

*If your study involves blood drawing or MRI add the following:*

**What are my rights if I take part in this study?**

You have the right to:

* be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* be given a description of any attendant discomforts and risks reasonably to be expected;
* be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* be given an opportunity to ask questions concerning the experiment or the procedures involved;
* be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
* be given a copy of the signed and dated consent form; and
* be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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

Signature of Participant Date

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

Print Name of Participant

**Note:** If the participant lacks the capacity to consent, consent must be obtained from a legally authorized representative (LAR) of the participant, with a description of the LARs authority to act for the participant. **The LAR must be** **(1)** a health care agent appointed by the participant in a dual power of attorney for health care or similar document; **(2)** a court-appointed guardian of the person, **or (3)** next-of-kin in the following order of priority: spouse, adult child (18 years or older), parent, adult sibling (18 years of age or older), grandparent, adult grandchild (18 years of age or older), or close friend.

Include next signature lines if consent will obtain consent from a LAR.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_
Signature of Legally Authorized Representative Date

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

Print Name of LAR

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

Representative's Authority to Act for Subject

Always include:

**Person Obtaining Consent:**

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

Signature of Person Obtaining Consent Date

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

Print Name of Person Obtaining Consent

Include the following if PHI is being collected from the participant under this consent form:

*HIPAA regulations require the participant to give separate written permission (signature) for the use of their protected health information.*

Person Obtaining Consent HIPAA Authorization confirmation:



     Confirm the participant signed the VA HIPAA Authorization section of this consent form