**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 participate 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].

**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 and the standalone VA HIPAA Authorization (VA 10-0493) will be used.

*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 (VA 10-0493).