Participant Name: _____ Date:_____

Title of Study: **Developing and Testing a COVID-19 Vaccination Acceptance Intervention**

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study:

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study funded by the Department of Veteran Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we are hoping to better understand why some Veterans have been vaccinated against COVID-19 and others haven't. Your participation in this research will last about 1 to 2 hours.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct/personal benefits to you from taking part in this research study. However, the information we get from this study might help others. You do not need to come to the VA to participate. You can participate in this study entirely from home via telephone, which is especially important during the coronavirus pandemic. For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study will involve a time commitment on your part. In addition, some of the questions asked concern sensitive issues and may make you feel uncomfortable; however, these questions are similar to those asked when you have a health care appointment. For a complete description of risks, refer to the Detailed Consent section of this document.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to. You will not lose any services, benefits or rights you normally have through the VA if you choose not to participate.

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LSI Verification Date: NA

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WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is _____ *[Principal Investigator, Local Site Investigator as applicable]* at the [*insert name of VA facility*.] If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [*PI or LSI contact information as applicable]*.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This research study aims to better understand the factors as to why some Veterans have been vaccinated against COVID-19 and others have not. The institution and investigators are receiving a grant from the Department of Veteran Affairs to support this research. There are no conflicts of interest to report between the investigators and Department of Veteran Affairs.

The Principal Investigators for this study are from the San Francisco VA Health Care system (SFVAHCS) and from the Central Arkansas VA Healthcare System (CAVHS). They have prepared this consent form so that you can learn what our study is about and, if you are eligible, so you can decide if you want to participate. Participation in research is completely voluntary, and only those who really want to participate, should participate. You don't have to participate, and you may end your participation in this study at any time.

Why is this study being done?

The overall purpose of this study is to better understand why some Veterans have been vaccinated against COVID-19 and others have not.

How many people will take part in this study?

We expect that about 450 Veterans will take part in this study across two VA Networks in the United States.

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You are being asked to take part in this study because you:

- Had one or more visit(s) at a participating VA clinic since the start of the trial****AND*****
- You have either:
  - Not started COVID-19 vaccination
    ****OR****
  - You received your most recent dose of the primary series of a COVID vaccine within the past 150 days.

HOW LONG WILL I BE IN THE STUDY?

It will take you approximately one hour to complete the survey. If you are invited to participate in an additional one-hour interview, you will be in the study for a total of two hours. The research study is expected to go on for approximately two years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

1. You will participate in one phone survey during which you will answer a series of questions. All surveys will be conducted over the telephone by the research staff. The survey will be approximately 45 minutes.

2. You may also be invited to participate in a single telephone interview asking your opinions and experiences about COVID-19 vaccination. If you are selected for the telephone interview, you will be contacted by one of our researchers at a separate time, and this will take approximately 60 minutes.

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

1. Keep all scheduled study appointments: This includes:

   a. Attending the scheduled telephone research appointment.
   b. Having a working telephone.

2. Letting the research staff know if you need to miss an appointment and rescheduling as close to the original study appointment as possible.

3. Asking questions of the study team as you think of them.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study are unlikely to have risks or cause side effects. Rare, unknown, or unexpected risks also may occur. For Veterans, some of the questions asked concern sensitive issues (such as questions about mental health symptoms or other health behaviors. Being asked some of these questions may make participants feel uncomfortable, however the questions asked do not fall outside what would normally be asked during a health care appointment.

There is always a chance that any procedure can harm you. The procedures in this study are not different from those you might experience in usual VA health care. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, by participating in this study you will be helping VA clinicians learn new approaches to COVID-19 vaccine acceptance that may help other Veterans.

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

You are free to choose to not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits and you can still get your care from the VA and other healthcare facilities the way you usually do. Whether you decide to participate in this research or not you can receive standard care outside of this research study. You may discuss these options with your health care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The information collected for this study will be kept confidential. All electronic files containing any information about you (such as your phone number and address) will be kept on a password protected VA server behind a secure firewall. A research record will be created because of your participation in this study, but your personal information, such as your name and any other identifying information, will be separated from the information you provide as part of the study assessments. No individual identities will be used in any reports or publications resulting from this study.

There are times when we might have to show your records to other people. Therefore, complete confidentiality cannot be guaranteed. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Additionally, identifiers might be removed from your identifiable private information and the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical 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 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. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as medication history, HIV status, COVID-19 status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of study oversight. Others may include the following: Office of Human Research Protections (OHRP), VA

Office of Research Oversight (ORO), Government Accountability Office, VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

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

While this study is being conducted you will not have access to your research-related health records.

Your participation will not affect your VA healthcare, including your health care provider's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization in writing at any time. To revoke your authorization, you must write to the Release of Information Office at your 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 VA patient to treatment or benefits 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.

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

Costs to Participants*:*
You will not be charged for any treatments or procedures that are part of this study.
If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications while in the study. If you chose to take time off work for research visits, you will be responsible for the cost associated with taking time off work. If you choose to seek services outside the VA, you may be responsible for those additional costs.

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Payment Offered for Participation:
For your participation in this research, you will be compensated $50 for completion of the telephone survey. You may also receive an additional payment of $50 if you are contacted for and complete a telephone interview about your opinions and experiences during this research study.

You will receive your payments through Electronic Fund Transfer (direct deposit) into your bank account or we will mail your payments to you via check at the address you provided. To process the payment, you may be required to provide electronic payment information if it is not already on file with [insert local VA], including your name and address, your social security number, your bank's name and address, your bank account and routing transit numbers. Only research staff working on the project as well as VA employees that process the payment will have access to the banking information you provide.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost unless the injury is due to your not following the study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Should you have a medical concern or get hurt or sick because of taking part in this study, you may call the following numbers:

NON-URGENT

[INSERT LOCAL SITE INVESTIGATORS]

URGENT
National Veterans Crisis Line Number: 1-800-273-8255

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Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether to take part in this study. If you decide to participate, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part in this study, you can still receive all usual care that is available to you. Your decision to not to take part will not affect the relationship you have with your health care provider or other staff at the VA or in the community and it will not affect the usual care that you receive as a VA patient.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You may be withdrawn from this study if it is determined during the interview that you are actively suicidal or otherwise experiencing very serious medical or psychological problems (requiring hospitalization) or for other reasons (e.g., altered mental status, intoxication, inappropriate behavior toward research staff). In addition, if clinically indicated, we will work with your treating provider and referrals will be made. If you are withdrawn you can continue to receive all VA health care benefits and services.

WHOM DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any further questions, you may call

[INSERT Local Site PI and local site coordinator name and contact information]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

FUTURE USE OF DATA

If you agree to take part in this study, the data that we gather will be analyzed and published. Identifiers, such as name, dates, and addresses will be removed, and the de-identified

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LSI Approval Date: NA

LSI Verification Date: NA

information will be used for future research without additional informed consent. In addition, these de-identified datasets may contribute to a central database accessible to other researchers in the future. Your data will be combined with data from other people taking part in this study. Your data may be combined with data from people taking part in other studies. Your identity cannot be determined from these shared datasets. Any papers, presentations, or reports of the results of this study will not identify you in any way.

AUDIO RECORDING

If you are invited to participate in the phone/computer interview, you may be audio-recorded as a part of this study (audio recording only, no photographs or video recordings will occur). You can still participate in this study if you do not wish to be audio recorded.

You will be asked to formally give your consent to be recorded after the recording begins before the interview is started. Audio recordings will be done for the purpose of qualitative analysis. The audio recordings will be transcribed prior to analysis. No identifying information about you will be contained in the transcription.

Prior to recording the interview, you will be reminded to avoid using your name or any other information that would personally identify you or anyone else.

Do you consent to be audio recorded?

□ **yes**
□ **no**

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study staff has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. 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	_____ Participant's Signature	_____ Date

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