Impact of Veteran Voices & Visions Peer Support Groups on Social Integration for Veterans with SMI/Psychosis

NCT05562674

February 23, 2024

Participant Name: _____ Date:_____

Title of Study: Pilot Randomized Control Trial (RCT) of Veteran Voices & Visions (VVV) Peer Support Groups for Veterans with Unusual Experiences

Principal Investigator: Dr. Ippolytos Kalofonos VA Facility: Greater Los Angeles Healthcare System

Invitation and Key information

We invite you to take part in a study called "Pilot Randomized Control Trial of Veteran Voices & Visions (VVV) Peer Support Groups for Veterans with Unusual Experiences." We are trying to learn more about and compare how well two support group approaches may work for Veterans who hear voices and have other unusual experiences. You are being invited to participate because you are a Veteran who receives care at the VA and has reported unusual experiences like hearing voices or seeing visions or has been diagnosed with psychosis.

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 to you and/or to the future population of individuals you represent. The following information is provided to help you decide whether to participate in this study.

Please ask the investigators or staff any questions you may have about the study. You can discuss it with your friends and family, or your health care provider, before making your decision. **Research studies are voluntary, and you are not obligated in any way to participate.** Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you do decide to take part, your signature on this consent form will show that you received and understand the information below, and that you consent to participate in this study.

What is the study about and how long will it last?

If you are willing to volunteer to be a part of the study, you will be randomly assigned to either a support group for healthy living and general health management or a support group that focuses on talking about mental health experiences. Both group approaches will have a supportive atmosphere that may help Veterans feel more connected to other Veterans and help you cope with mental health experiences. Each support group will run for 12 weeks and will be held virtually. You will be asked to participate in 3 questionnaires at the following intervals: before the support group begins, 12-weeks after the support group begins, and 12-weeks following that point. We anticipate entering 48 Veterans in this study. We hope the information we gather from this study will help us improve support groups for Veterans and will help us improve the care we offer Veterans with psychosis throughout the VA.

Reasons to participate

There are no direct benefits to participating in this study. You may experience greater understanding of your health experiences, by participating in support group conversations and research

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questionnaires . The information you provide may help the VA improve the lives of Veterans with similar experiences.

Reasons to not participate

Participation in this study does not affect your regular treatment at the VA. Data collection related to the training involves risks such as fatigue, distress, frustration, and risk of loss of privacy/confidentiality. These risks are comparable to other evaluations normally administered at the VA.

Voluntary participation

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

Contact information for questions/concerns

You can contact Dr. Ippolytos Kalofonos at [redacted] or [redacted]

Funding Disclosure

This study is being funded by the Department of Veterans Affairs Office of Rehabilitation Research & Development (RR&D) Small Projects in Rehabilitation Research (SPiRE) grant.

DETAILED PROJECT INFORMATION

What is the purpose of this stud

The purpose of this research study is to learn about and compare how well two promising support group approaches may work for Veterans with psychosis. One support group approach focuses on healthy living and the other focuses on talking about mental health experiences. Both support group approaches may help Veterans feel more connected to other Veterans and help you cope with mental health experiences. We hope the information we gather from this study will help us improve support groups for Veterans and will help us improve the care we offer Veterans with psychosis throughout the VA.

How long will I be in the study?

You will be a part of this research study for the month before your group starts and 3-months after the close of the 12-week support group. The first questionnaire will take place before your group starts and the final questionnaire will take place 3 months after the 12-week mark of support group sessions. Each questionnaire entails an interview about your current coping strategies and your

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understanding of your mental health experiences, including survey questions. We estimate the entire first questionnaire , done prior to starting the groups, to last up to 2 and a half hours. We estimate the second questionnaire , done after the 12th and last group session, to take up to 2 hours. We estimate the third and last questionnaire, done 3 months after the last group session, to take up to 2 hours. The total time of the questionnaires and the group sessions will be up to 7 months.

What will happen if I take part in the study?

Before any study-related activities, you will be asked to read and sign this consent document. Should you decide to participate in this study, in the same visit, you will be asked some questions about your background and medical history to determine if you are eligible to participate.

If you are willing to volunteer to be a part of the study, you will be randomly (i.e. by chance) assigned to either a support group for healthy living and general health management or a support group that focuses on talking about mental health experiences. Both group approaches will have a supportive atmosphere that may help Veterans feel more connected to other Veterans and help them cope with their mental health experiences. **The support groups will run for 12 weeks and will be held virtually. Each support group meeting lasts for 60 minutes**. You are not required to contribute to group discussion and may sit quietly throughout the session, as desired. We anticipate entering 48 Veterans in this study.

If you are assigned to the group focused on talking about mental health experiences, here are potential themes that will be covered, as well as discussion topics:

- Weeks 1-4: Sharing about your mental health experiences.
  - What would you like others to know about you?
  - What would you like to learn about others' mental health experiences?
  - How would you like to change or improve your mental health?
  - What have you found helps you live with your mental health experiences?
- Weeks 5-10: Reflecting on the meanings and origins of your mental health experiences.
  - How do you understand your mental health experiences?
  - What is your relationship to these experiences?
  - When do your mental health experiences become more intense or challenging?
  - What emotions or messages do you associate with your voices, visions, or other sensations or beliefs?
  - How would you like to change or improve your relationship to these experiences?
  - What was going on in your life when your mental health experiences began?
- Weeks 11-12: Incorporating new insights into your daily life.

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- What would your life be like if you form a better relationship with your voices, visions, and other mental health experiences?
- What inspires or energizes you? What is meaningful to you?
- What has it been like to talk with others who have gone through similar experiences?
- What from the group will you take with you or incorporate in your life moving forward?

The first 60min. session will begin with facilitators introducing the origins and purpose of the group, sharing about their own interest facilitating this group, and explaining that group discussions and activities are intentionally open-ended and will be determined by Veterans in the group. That means you can share with the group what is on your mind, which may or may not be related to your mental health experiences. In subsequent sessions, facilitators will have videos and worksheets available, if the group expresses interest in doing some structured activities.

Structured activities may include:

- Short videos on the Hearing Voices movement, from which this group draws.
- An optional worksheet that asks you to describe characteristics of an unusual sensation you have.
- An optional timeline worksheet that asks you to list positive factors and stressors that contributed to your mental health experiences throughout your life.
- An optional worksheet that asks you to describe characteristics of a challenging or difficult belief you experience.

If you are assigned to the support group for health living, here are the kinds of topics that will be covered along with potential questions used to start conversations:

- Group 1: Introductions and Overview
- Groups 2-3: Healthy Eating
  - How to read a food label
  - Serving Size
  - Liquid calories
- Groups 4-5: Exercise
  - Benefits
  - Barriers and ways to overcome them
- Group 6: Building Healthy Sleep Habits
- Group 7-8: Goal-setting

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  - What is a SMART goal?
  - Setting SMART goals
- Group 9: Mindfulness
- Group 10: Recreation for Leisure
- Group 11-12: Problem Solving

Each 60min. session will begin with a short introduction to the skill, followed by a video demonstrating how and when to use the skill, a discussion about challenges to use the skill and ways to overcome these barriers, and a discussion about potential results or improvements that could come from using this skill.

You will be asked to complete **3 audio-recorded** questionnaires with the research team. These include a questionnaire before the support group starts, immediately after the groups have run for 12-weeks, and 3 months after that point. These questionnaires will be done virtually over video call or phone call at a time that is convenient for you. They will include answering questions about psychiatric and medical history, current symptoms, social relationships, and your perspectives and experiences. Some questions will be conversational, and others are survey questions that will ask you to answer yes or no or with a number. An outline of these questionnaires is provided below:

1. Pre-intervention questionnaire (2.4 hours in total)
   a. Interview (45 min)
   You will be asked about your mental health symptoms, how they came about, and how you cope with them.
   c. 14 survey questionnaires (100 min)
   These questionnaires are designed to gather information about your medical and mental health history and your social history, along with information on the level of distress you feel due to your mental health symptoms, beliefs in your ability to succeed in a given situation, and your level of connection to loved ones and your community. These questionnaires will also ask about your experience of self-stigma, your beliefs on illness management and recovery, and your use of health care services.

2. Post-intervention questionnaire(2 hours in total)
   a. Interview (45 min)
   You will be asked about your experience in your group, including what you like, what you do not like, what you have learned, and suggestions for improvements that could be made. You will also be asked about any changes to the way you understand your mental health experiences,

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such as voices, visions, or other sensations or beliefs, as well as any new coping strategies you learned as a result of participating in the group.

b. 14 survey questionnaires (75 min)

These questionnaires are designed to gather information about the level of distress you feel due to your mental health symptoms, beliefs in your ability to succeed in a given situation, and your level of connection to loved ones and your community. These questionnaires will also ask about your experience of self-stigma, your beliefs on illness management and recovery, and your use of health care services. You will also be asked to complete a short survey on your level of satisfaction with attending the group.

3. Post-intervention questionnaire(1.9 hours in total)

a. Interview (45 min)

You will be asked about your experience in your group, including what you like, what you do not like, what you have learned, and suggestions for improvements that could be made. You will also be asked about any changes to the way you understand your mental health experiences, such as voices, visions, or other sensations or beliefs, as well as any new coping strategies you learned as a result of participating in the group.

b. 13 survey questionnaires (70 min)

These questionnaires are designed to gather information about the level of distress you feel due to your mental health symptoms, beliefs in your ability to succeed in a given situation, and your level of connection to loved ones and your community. These questionnaires will also ask about your experience of self-stigma, your beliefs on illness management and recovery, and your use of health care services.

While your group is running, you will also be asked to fill out **a weekly, 5-minute survey** about your experience in the group. The survey link will be emailed to you after each group session, and you should plan to fill it out as soon as the group ends.

We are planning to **video-record** group sessions. Participating in this study means that you agree to be video-recorded. If you do not want to be recorded, you will not be able to participate. These video recordings will be reviewed by members of the research team, and key interactions and activities of group sessions will be noted. The recordings will enable us to assess how well facilitator are following their guidelines as well as understand how groups come together, how Veterans participate in group activities, and how groups may affect Veterans' health. We will compare similarities and differences across the 2 types of groups. These videos will be securely stored on an encrypted and password protected VA research server.

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After you finish participating in the final questionnaire, 3 months following the end of the 12-week group, your participation in this research project will be complete.

What possible risks and discomforts might I have if I take part in this study?

This study poses some risks to Veterans that are comparable to other evaluations normally administered at the VA. These risks include:

- Risk of fatigue. There is a risk that you will find the questionnaires, interviews or the group sessions tiring. In that event, it is fine to let the interviewer or group facilitator know you would like to take a break or stop for the day.

- Risk of distress and frustration. There is a risk that the questionnaires, interviews or the group sessions may stir up some challenging emotions and cause you distress and frustration. If that is the case, you can let the interviewer or group facilitator know and they will be able to take a break and address these feelings in whatever way is appropriate and helpful, whether it is taking a break or having a conversation about it.

- Risk of loss of privacy/confidentiality. There is a risk that private information you share, despite our best efforts to keep it private and secure, may somehow get out and impact your reputation among friends or family, standing with VA staff or leadership, or otherwise lead to adverse financial or emotional consequences. You are free not to share any sensitive personal information as you wish, and this will not affect your participation. We will also do our best to protect your privacy and confidentiality.

During the questionnaires, it is possible that you might not want to answer some questions because they make you feel uncomfortable; that is fine, you can skip any questions that you want to. You can choose to skip any questions that cause discomfort or can stop doing the questionnaires by telling the interviewer you want to stop. You can stop doing the questionnaire at any time, take a break, or continue the questionnaire at another time.

During support group sessions, you are welcome to take breaks as necessary. Group co-facilitators are trained to note signs of distress and may check in with you during or after the group meeting to see if you need additional support.

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For all study related activities, including support group sessions, we will ask you to be a quiet, private location. The research team will be available to you, family members, and clinicians for any concerns that arise regarding the study.

Although this study does not involve procedures that would be expected to increase suicidal thoughts or suicide risk, it is not uncommon for Veterans to have periods of suicidal thoughts. Some of the measurement procedures may identify such suicidal thoughts. If you are experiencing a high level of distress, an emergency protocol will be followed if necessary. In addition, the PI is a psychiatrist and, if deemed appropriate, will call you separately to check in and assess the need for further intervention, such as reaching out to the VA Crisis Line, presenting to the emergency room, or calling 911 to have emergency personnel come to you.

What are the possible benefits of participating in this study?

There are no direct benefits to participating in this study. You may experience greater understanding of your health experiences, by participating in support group conversations and research questionnaires. The information you provide may help the VA improve the lives of Veterans experiencing psychosis.

Alternatives to Participation

You may choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Refusal to participate will not affect your experience at the VA. The intervention is not a part of standard therapy, and as such, there are no alternatives to participation in this study. If desired, you can discuss options for joining an alternative support group with your mental health provider.

How will my private information be protected?

As in any research study, it is possible that personal information about you could become known to other people. The research team will take precaution to prevent this from happening. Your name will not appear on any survey you complete during the study. Instead, all surveys you complete will be coded with a study ID.

The data collected in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. The only exception is that if you express plans to hurt yourself or another person, then we cannot guarantee we will be able to continue to protect your privacy and confidentiality. The research team may be required to contact

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others who are qualified to intervene. Outside of that, confidentiality will be maintained in the following ways:

- We will keep a secure file on our VA research server, which is behind a private firewall that links your name to a random code number. All of your answers to questions that we ask are only labelled with the code number, not your name. Only the study PI and the study staff with relevant privileges can look at this file that links your name to the code number.
- The digital audio and video recorders we use are approved by the VA and the files it creates will be encrypted. Group sessions are video and audio recorded. They are reviewed to give feedback to the group facilitators to help them improve their facilitation. We are also interested in learning how and why different groups have different kinds of discussions and interactions and how Veterans respond to the group. Portions of the questionnaire interview will be audio recorded and professionally transcribed by the VA transcription service at Salt Lake City VA. The recordings will remain within the VA, and will not be transferred to an external entity. All recordings are immediately saved within our VA secure network and will only be accessed by research staff for the purposes of this project. They will never be made public or accessible beyond the purposes of this study.
- Answers to the questions we ask, all recordings, and other data created from this study will be stored electronically behind firewalls on a VA research server.
- Only VA approved research staff can look at your responses to questions.
- Any paper documents that we have for this study are always kept in locked cabinets at the VA Greater Los Angeles.

When we use the data collected and report the findings, we use information in ways that disguise individual identities and that combine the data we have gathered. That means we report the findings of this study in such a way so that no one can figure out who participated in our study. Relevant findings may be included in talks or papers about this study, but no findings will be shared with you as an individual. Any talks or papers about this study will not identify you. No data will be shared in future research. Description of this clinical trial, NCT05562674 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 a summary of the results. You can search this website at any time.

Sharing of Individual and Overall Research Results

This is a study which is not designed to give us any information about your health. Generally, evaluations (i.e., surveys) done for research purposes are not meant to provide clinical information and therefore no survey results from this study will be shared with you. Individual interview transcripts may be shared with you, if desired.

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Payments offered for participation

You will receive $25 per hour of **questionnaires** and $5 for completion of a brief survey immediately following each support group session. Participants will be eligible for up to $285. Payment will be provided via agent cashier voucher, canteen voucher, direct deposit, or gift card, depending on your preference.

The IRS requires research institutions to report compensation to clinical trial participants if the amount is $600 or more a year. With few exceptions, study reimbursements are considered taxable income reportable to the Internal Revenue Service (IRS). A Form 1099 will be sent to you if your total reimbursements for research participation are $600.00 or more in a calendar year. A third-party vendor will send you IRS Form 1099 as a record of this payment for you to include with your tax return. Reimbursement of expenses is not considered compensation. If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

What will happen if I am Injuries because of my participation 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 to you unless the injury is due to non-compliance by a study participant with study procedures or if research activities are conducted for VA under contract with an individual or non-VA institution. This care may be provided by the West LA VAMC or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the West LA VAMC at 310-748-3711 and ask the operator to connect you to the medical administration service.

If you should have a medical concern or get hurt or sick as a result of taking part of this study, call:
DURING THE DAY:

- Contact Dr. Ippolytos Kalofonos at [redacted] or Mariam Nazinyan at [redacted]

AFTER HOURS (emergency for psychiatric or medical issues:

- Contact Dr. Ippolytos Kalofonos at 3[redacted]
- Dial 911 or go to your nearest emergency room
- You may also use the Veterans Crisis Line. The Veterans Crisis Line is staffed 24/7 with full time, caring, Department of Veterans Affairs mental health professionals. The toll-free hotline is confidential. You can also go online to chat with someone on the Crisis Line, and you can also send a text to **838255**. The phone number Veterans can call is **1-800-273-8255**

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– just **PRESS 1 IMMEDIATELY TO BE CONNECTED TO THE VETERANS HOTLINE.** The Web address is **VETERANSCRISISLINE.NET.**

Do I have to take part in this study?

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. You will be told of any important new information that is learned during this research study, which might affect your willingness to continue participation in this study.

Participant termination from study without consent

The Investigator may decide that you will need to be withdrawn from this study without your consent, at some point throughout the course of the study. An anticipated reason for termination of the study may involve the onset of a health condition that, in the opinion of the Investigator, would compromise your safety or the quality of data.

Participant withdrawal

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled, and your decision will not affect your health care treatment at the VA.

If you want to stop being in the study, you should tell the investigators or study staff. You can do this by phone by calling us at 310-210-4231. You should ask for a HIPAA revocation form, which you can sign to revoke any data collection, which does not require your participation. The study staff can provide this to you, upon request.

Who do I contact about this study if I have questions?

You can contact Dr. Ippolytos Kalofonos at [redacted] or [redacted]. 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 Greater Los Angeles Institutional Review Board (IRB) at (310) 268-4437. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the local VAGA IRB if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

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Future use of data/specimens (materials)

Participants will not be contacted for future research following the completion of this study. After identifiers are removed, your data could be used for future research without additional consent. The data will be stored on an encrypted and password protected VA research Server.

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 Name, probable psychiatric diagnoses; Vet or non-Vet; alcohol / substance use disorder (if any); current medications (if any); head trauma (if any), loss of consciousness (if any), and neurological conditions (if any), other medical conditions (if any). We will request the following kinds of data from, mental health stop codes containing relevant mental health diagnoses as well as attending a GLA appointment within the past 12 months. We may review CPRS to confirm psychiatric diagnostic and medical history and past and current medications, as well as current contact information (mailing address, email, phone number) for the Veteran.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: the VA Institutional Review Board, the local VA medical facility Human Research Protections Program and Centralized Transcription Services Program (CTSP) to transcribe audio recordings.

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 may request a copy of the transcript of your own interview, but otherwise will not have access to your research related health records. This will not affect your VA healthcare, including your doctor'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.

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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, Dr, Ippolytos Kalofonos and his 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.

Adequate time and opportunity to consider whether to participate in this study:

If you so desire, you may keep a copy of this document to read again and discuss with those close to you. In that case, should you decide to participate, you may return for your first study visit and sign the form at that time, after further discussion with one of the study investigators. **AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Dr./Mr./Ms._____ has explained the research study to you.

By signing below, you indicate your agreement to participate in this research study and acknowledge the following:

- You have been told of the risks or discomforts and possible benefits of the study.
- You have been given the chance to ask questions and obtain answers.
- You have read and understand this consent, or it has been read to you.
- You have read and understand the California Experimental Subjects Bill of Rights, provided below.
- You will receive a copy of this consent after you sign it.

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California Bill of Rights of
RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an 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.

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SIGNATURES

By signing, you are agreeing to volunteer 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. Your signature also confirms that The California Bill of Rights of Human Subjects in Medical Experiments has also been given to you. A copy of this signed consent will be retained in the investigator's research records. (if appropriate add: A copy of this signed consent will be retained in your VA medical record).

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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