Official title: Feasibility Study of Compassion Meditation Intervention for Older Veterans in Primary Care with Anxiety or Mood Disorders

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Study Title: Feasibility Study of Compassion Meditation Intervention for Older Veterans in Primary Care with Anxiety or Mood Disorders	
Principal Investigator: Barton W. Palmer, PhD	
VA Facility: Veterans Affairs San Diego Healthcare System	
Participant Name:	**Date:**

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about compassion meditation – we want to find out if a compassion meditation training group can be helpful for Veterans age 55 years or older identified through VA Primary Care who have concerns with anxiety and/or depression. In this initial "feasibility" study, we are examining whether the participants like/accept this approach, and whether it needs modification. We also want to examine a different group focused on providing information about healthy aging – our goal with this other group is to see if it is a useful comparison to the compassion meditation group. Our plan is to use this information to help us design a future larger and more definitive research study on the effectiveness of compassion meditation in helping Veterans.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

The study involves 10 weekly 90-minute virtual group sessions. Depending on which condition you are being recruited for, this will involve either 10 virtual compassion meditation group training sessions or 10 virtual educational sessions about healthy aging. (You will be told which type of group you are being recruited for before you decide whether or not to participate).

Regardless of which type of group you are recruited for, participation will also involve two additional virtual study visits (estimated time for these is approximately 45-90 minutes each) where you will be interviewed about, and asked to complete questionnaires about you feelings or symptoms (such as depression and anxiety), as well as other measures of psychological factors, health, and well-being. In addition, the study team will ask you questions about your possible exposure to the COVID-19 virus, positive COVID-19 test(s), and COVID-19 vaccination status. You may be asked to give approximately 2 to 3 teaspoons of blood at two timepoints (one time before you start the training program and again after you complete the program) so that we can examine certain measures of inflammation, i.e., to see whether or not the training has an effect on inflammatory processes.

A copy of this document will be provided to the research participant.

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Your participation in this research will last about 3 months. In order to participate, you must plan to attend the 2 individual study visits and the 10 group sessions all occurring virtually.

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

There may or may not be a direct benefit to you from these procedures. The investigators, however, may learn more about what modifications are needed in the training and measures as they prepare a future larger study. The larger study may help investigators find out if group trainings are helpful for Veterans in Primary Care ages 55 or older with anxiety and/or depressive symptoms.

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

It is possible that your anxiety and/or depressive symptoms may either not change or may worsen in the absence of a standard psychotherapy treatment.

The possible blood draws may be associated with some discomfort, bruising, or bleeding typically associated with standard venipuncture. Also, there is the small risk of local infection. In rare cases, some people may feint.

As with any study involving human participants, a risk of disclosure of personal material also exists. The compassion meditation and psychoeducational healthy aging groups will be conducted in a group format, and thus a further risk of loss of confidentiality exists because other participants will be privy to information you may reveal during the group sessions. Participants will be reminded of the importance of keeping information about others in the group confidential. The group training sessions may be video recorded using an external video camera or through the CISCO WebEx Program and reviewed by a member of the study team as part of the therapist's supervision. Your face and voice will be recorded in the video recordings.

The alternative to participation is to receive treatment for anxiety or depression through VA clinical (non-research) mental health services. You may also talk with your physician about other options for treating anxiety and/or depression symptoms.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Barton Palmer, PhD, of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is (858) 642-3505.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Barton Palmer, PhD, and his colleagues at the VA San Diego Healthcare System are asking for your consent to this research. This study is being sponsored by the Department of Veterans Affairs.

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The purpose of the research is to find out the feasibility of using a compassion meditation training group to help Veterans in Primary Care ages 55 or older reporting mild to moderate anxiety and/or depressive symptoms. We are also examining whether an educational healthy aging group is an appropriate comparison to the compassion training group. We will use the information from this initial study to find out what modifications may be needed before designing a future larger and more definitive study about compassion meditation. You are being asked to participate because you have reported mild-to-moderate anxiety and/or depressive symptoms and you are 55 years or older.

Approximately 40 Veterans will take part in this research at the VA San Diego Healthcare System (there are no other sites in the study).

Many older Veterans in VA primary care clinics experience anxiety and depressive symptoms, but only a minority of these Veterans seek care through VA mental health services. Prior research with civilians, including one study of Veterans with PTSD, suggests a strengths-focused intervention that provides group training in compassion meditation may be effective in reducing negative emotions and increasing positive emotions and well-being. But this has not been tested in older Veterans with mild-to-moderate anxiety and/or depression, and we don't yet know for certain what modifications to the training might be needed to make the group most useful. We want to do a future larger and more definitive study comparing compassion meditation to a healthy aging educational group, but before conducting the larger study, we want to do a smaller study to check the feasibility and whether participants like and accept the groups. The information from the study will guide and support development of a larger-size, more definitive study, planned as the follow-up after this project.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take approximately 3 months. The overall study will last approximately 2 years. The study will involve 12 visits:

- 1 initial individual study visit lasting 45-90 minutes,
- 10 weekly group sessions of 90 minutes each,
- 1 final individual study visit lasting 45-90 minutes.

After the final study visit, your participation will be complete.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you decided to participate, the following will happen:

All study procedures will take place virtually through programs called Veteran Video Connect (VVC) and Cisco WebEx, which will allow you to see, hear, and speak with Dr. Kangas and the other group participants using your computer, tablet, or smartphone. Both VVC and Cisco WebEx meet VA privacy and security standards.

Visit 1: You will meet virtually via VVC or Cisco WebEx with one of the study staff to be interviewed and complete questionnaires regarding psychological distress, compassion, empathy, mindfulness, social connectedness, well-

being, resilience, optimism, wisdom, and happiness. Additionally, you will be mailed a questionnaire packet to complete at home. When completed, you will send it back to the study team using the pre-addressed and pre-paid envelope included in the packet. Unfortunately, there is a risk that your completed packet with be lost in the mail on the way back to VASDHS. However, this completed packet will not contain any of your personally identifiable information. If needed, we may request that you complete some of the study assessments for a second time for added compensation. If possible and safe due to the COVID-19 situation, we will also ask you to go to the VA Clinical Laboratory to have approximately 2 to 3 teaspoons of blood drawn, one time before you start the training program and again after you complete the program. The blood samples will be analyzed for researching measures of inflammation so that we can explore whether or not the training has an effect on inflammatory processes.

We will also ask you questions about your age, education, gender, relationship status, medical conditions, and active medications, and may review your VA electronic medical records to confirm details about your medical conditions and medications.

Visits 2 through 11: Next, you will participate in either of the following groups virtually via VVC or Cisco WebEx (you will be told before consenting which type of group you are being recruited for – this depends on where we are in terms of completing this study and groups available at the time of recruitment). The amount of time between Visit 1 and starting the groups may also vary depending on how quickly the groups are filled, but we will give you our best estimate before you decide whether or not to participate.

A. Compassion Meditation Training: The compassion meditation training involves 10 virtual weekly 90-minute group sessions (our goal is to have up to 10 Veterans in each group). Sessions 1 - 4 assist participants in basic mindfulness breathing practices; sessions 4 - 8 focus on personal analysis of factors underlying difficulties with compassion for self or others; the final two sessions (9 and 10) review content and assist with relapse prevention.

B: Psychoeducational Healthy Aging group: This will involve 10 virtual weekly 90-minute group sessions wherein you will watch and discuss a series of videotaped lectures by experts in healthy aging, covering topics such as happiness, nutrition, mental resilience and health, and physical activity. After viewing the informational videos there will be a group discussion about the information in them. As this is the initial feasibility study, the specific topics covered may vary as we learn more during the course of the group about which types of information are most interesting and useful for participants.

Regardless of which group you are assigned to, we will ask you to complete a brief questionnaire before each group session to measure your level of positive emotions during the course of the groups. You will also be asked to complete at-home questionnaires and structured practice sessions that will help reinforce the concepts you learned in the group sessions. Audio files of the at-home practice sessions as well as appointment reminders and directions to the clinic will be emailed to you from a VA-secure email program. On a weekly basis, a team-member will review these at-home practices and questionnaires with you virtually.

The group training sessions may be video recorded using an external video camera or through the CISCO WebEx Program and reviewed by a member of the study team as part of the therapist's supervision.

Visit 12: Within 1 to 2 weeks after the final group session, you will again meet virtually with one of the study staff to complete the final study assessments. Additionally, you will be mailed a final questionnaire packet to complete at home. When completed, you will send it back to the study team using the pre-addressed and pre-paid envelope included in the packet. Unfortunately, there is a risk that your completed packet with be lost in the mail on the way back to VASDHS. However, this completed packet will not contain any of your personally identifiable information. If needed, we may ask you to complete some of the questionnaires for a second time for added compensation. Lastly, if possible and safe due to the COVID-19 situation, we will ask you to go to the VA Clinical Laboratory to have approximately 2 to 3 teaspoons of blood drawn before and after you complete the 10-week training program. The purpose of re-collecting this information is to determine if there are any changes following group participation. We will also include a few brief questionnaires and interview about your impression of the groups. Visit 12 is expected to take about 45 to 90 minutes.

For all questionnaires, you can skip any question that makes you uncomfortable and you can stop at any time.

Although compassion meditation has been found useful in non-Veterans, it has not been evaluated in older Veterans with anxiety or depression, so is considered experimental for this purpose.

As part of your participation, you are expected to:

- Complete the questionnaires and interviews,
- Participate in the groups and ask questions as you think of them,
- Be polite and cooperative with the study staff and other participants,
- Keep the identify of other group participants confidential,
- Inform the research staff, group leader, and/or study investigators if you have concerns or if you choose to stop participating.

If you choose to stop attending the groups, we will ask you if you are willing to complete the final follow-up visit, but whether you do so is voluntary.

You are also expected to keep track of your study appointments. If you miss an appointment/virtual visit, please contact Dr. Palmer or his Research Team at (858) 642-3505 to reschedule as soon as you know you will miss the appointment.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

All of the procedures and measures described above are for research purposes only. They not part of standard care for your anxiety or depressive symptoms.

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

Any study procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- The study procedures and assessments require time and concentration. You may become bored, fatigued, or distressed while undergoing these assessments and/or while participating in the study group sessions. If, for any reason, you wish to not answer specific questions or you wish to terminate the session, you will be able to do so.
- It is possible that your symptoms of anxiety and/or depression may either not change or may worsen in the absence of starting standard psychotherapy during study participation.
- The blood draws may be associated with some discomfort, bleeding, or bruising. Rarely, fainting occurs because of drawing blood.
- As with any study involving human participants, a risk of disclosure of personal material also exists. The compassion meditation and psychoeducational healthy aging groups will be conducted in a group format, and thus a further risk of loss of confidentiality exists because other participants will become aware of information that you reveal during the group sessions. You can choose not to reveal any personal or confidential information during the group sessions.
- As with any study involving the use of postal mail for the mailing of documents, a risk of losing documents in the postal system also exists. The study team safeguards your personal information by pre-addressing all envelopes for the material you are asked to mail back to the VA. Additionally, the study team only requires you to only include the most necessary of information.
- As with any study involving electronic signature platforms, a risk of disclosure of personal material also exists. However, DocuSign is a VA HIPAA-compliant Zoom platform which allows you and other Veterans to sign and return the consent forms immediately online via the platform. The VA has specific safeguards to minimize the risk of loss of confidentiality include the following: (1) Consent and other forms containing identifying data will be kept separate from other research data. If providing consent via an online platform such as DocuSign, this platform will be kept separate from any other identifiable research data., (2) All hardcopies of the signed consent forms are only printed in a VA facility and again, stored in a locked cabinet separate from other documents and identifiable research data.

In addition to the risks described above, you may experience a previously unknown risk or side effect. You will be informed if the researchers learn of any change in the amount of risk to you. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this facility or loss of benefits to which you are entitled.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. If you participate in the healthy aging educational group you may learn information that you might find useful or interesting such as information about positive mental health factors such as resilience, and other things like exercise, diet, or nutrition. If you participate in the compassion meditation group, you may learn meditation methods that you

might find helpful in increasing your positive emotions, reducing negative emotions, and improving social connectedness.

The investigators may learn more about what modifications are needed in the training and measures as they prepare a future larger study. The larger study may help investigators find out if group trainings are helpful for Veterans in Primary Care ages 55 or older with anxiety and/or depressive symptoms. This could ultimately help future Veterans with anxiety or depressive symptoms.

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

The alternative to participation is standard care through the standard VASDHS services for providing mental health care. There are a number of established treatments for anxiety and depression, such as cognitive behavioral therapy, acceptance and commitment therapy, and/or medications. You should discuss these alternative choices with your primary care physician to choose what is right for you.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study, you will be notified if any important new information is found that may affect your willingness to continue.

If the results of this research might influence your medical care after you have completed participation, the Research Team will contact you to let you know these results.

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

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance, but no additional compensation is available.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this facility or loss of benefits to which you are entitled. If you decide to discontinue participating, please inform a member of the research staff or investigators. The investigators may continue to review the data already collected for the study but will not collect further information without your permission, except from public records, such as survival data. Data from the blood samples already analyzed cannot be withdrawn, but the sample themselves may be destroyed.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The group leaders, research staff, and/or investigators may also withdraw you from the study if they believe your participation is contraindicated (e.g., if you symptoms are getting noticeably worse, or if you are non-cooperative or disruptive in the group sessions or study visits), of if they believe it is in your best interest to discontinue participation.

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

There will be no costs to you or your insurance for any procedures or testing done as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Palmer or his Research Team at (858) 642-3505 so they can check into and correct the situation.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive payment for participation at the two (non-group) study visits: $100 for the first visit and $150 for the final visit, for a total of $250 for complete participation. In addition, if the COVID-19 situation permits, there is a possibility for two separate blood draws of 2 to 3 teaspoons each. One will take place around the time of the pre-training visit and the other around the time of the post-training visit. For each of the blood draws you will receive $50, for an additional total of $100. You will have an opportunity to receive up to $350 for completing the study. Also, if you are asked to repeat study assessments, you will be compensated an additional $20 for your time. Whether or not the blood draws are safe to occur is up to the discretion of the study team. The decision to partake in the blood draws is up to you as the participant. Declining the blood draws does not impact your eligibility for participating in the trainings or other aspects of the study. Payments will be made directly to your bank account using electronic funds transfer or by certified check. Payments could take up to 90 business days to be deposited into your account. **If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.**

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

If you have any questions, complaints, or concerns about the research or other related matters, you may contact the Research Team at (858) 642-3505.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study-related questions or concerns, you can contact the Research Team at (858) 642-3505.

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DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?

This study will not involve genetic research or genome sequencing. No DNA will be extracted from your blood samples.

FUTURE USE OF DATA AND RE-CONTACT

Data from this study will be retained for future research by the study team.

We may wish to contact you in the future about participating in future studies for which you might qualify. Only people within the VA would be contacting you if this were to occur. You can agree to or decline this option, by checking the appropriate box below.

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

HOW WILL MY SPECIMENS BE USED?

Blood samples will be processed and analyzed in Dr. Hauger's research laboratory (one of the co-investigators for the current study). This will be done to determine levels of certain research blood-based biomarkers of inflammation. (These are research measures and are not used for your clinical care.) The blood samples will be destroyed after processing. Until processing, however, your blood will be stored with a coded label that does not identify you.

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Because the study involves a group treatment, a note in your VA medical record describing participation is required following each study visit.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

In addition, digital video recordings of your training sessions may be reviewed by a study investigator who is an expert in compassion meditation training. These recordings will be stored as digital files behind the secure VASDHS firewall and may be reviewed here to be sure that treatment is being delivered as planned. All recordings will be made using an external video camera or the CISCO WebEx program and will be destroyed in compliance with the current VA Records Control Schedule.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify you.

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 a summary of the results. You can search this website at any time.

While this study is being conducted, you 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.

Any presentations or publications from this information will not identify you in any way.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. You may be asked to sign this form and mail it back to the research office at the VA San Diego Medical Center via USPS. Alternatively, you may sign this form electronically using DocuSign: a VA HIPAA-compliant Zoom platform. From DocuSign, you may download a copy of your consent form to keep, or the study team can mail it to you via USPS. As previously stated, the VA has specific safeguards to minimize the risk of loss of confidentiality include the following: (1) Consent and other forms containing identifying data will be kept separate from other research data. If providing consent via an online platform such as DocuSign, this platform will be kept separate from any other identifiable research data., (2) All hardcopies of the signed consent forms are only printed in a VA facility and again, stored in a locked cabinet separate from other documents and identifiable research data.

Dr. Palmer or _____ has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

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I agree to participate in this research study as has been explained in this document.

_____ _____
Participant's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

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Health Information Portability and Accountability Act (HIPAA)

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 document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information 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 medical history, mental health treatment, etc. Information about alcohol or substance use disorders and treatment will be collected. The study team will be collecting information on your possible exposure to the COVID-19 virus, positive COVID-19 test(s), and COVID-19 vaccination status. In addition, the last four digits of your Social Security number will be collected for accessing your medical record and for payment purposes.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other VA entities may include the Human Research Committee (HRC) and the VA Office of Research Oversight (ORO), Institutional Review Board (IRB), Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address:
Barton Palmer, PhD
3350 La Jolla Village Drive, MC 151
San Diego, CA 92161

If you revoke this authorization, Dr. Palmer 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.

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

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study; any study information that has been placed into the investigators' database may be used by the investigators for future research and will not expire.

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AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

A copy of this document will be provided to the research participant.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5

A copy of this document will be provided to the research participant.