Title: Improving Collaborative Decision Making in Veterans with Serious Mental Illness

ClinicalTrials.gov ID: NCT04324944

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Study Title: Improving Collaborative Decision Making in Veterans with Serious Mental Illness

Principal Investigator: Emily Treichler, PhD

VA Facility: San Diego

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 about a group therapy for Veterans who participate in services at the Center of Recovery Education (CORE). The group therapy assists people with serious mental illnesses to improve skills needed to engage in collaborative decision making with members of their treatment team. It is being funded by the VA's Rehabilitation Research & Development service.

By doing this study, we hope to learn

1. Whether the group therapy is helpful to Veterans participating in services at CORE, and
2. Whether we should make any changes that would make the group therapy more likely to be used in VA settings like CORE as a part of regular care.

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

You will be asked to participate in a group therapy at CORE that meets for one hour per week for ten weeks, and complete up to seven hour-long assessments. You will also be asked to allow the study team to audio-tape some of your VA mental health treatment appointments.

Your participation in this research will last about five months total, although the time needed to complete all study activities is approximately 20-25 hours.

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

1. You may find the group therapy you participate in helpful.
2. This study could help other Veterans who are receiving care at the VA.

For a complete description of benefits, refer to the Detailed Information section of this consent.

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

1. You may feel anxious or uncomfortable during the study when thinking about or talking about problems you may have experienced when seeking mental health care or from being in a group setting.

A complete description of risks is included in the Research Details Study Risks section.

Participation is voluntary and the only alternative is to not participate. Whether or not you participate in this study, you will still have full access to CORE services.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Emily Treichler, a psychologist at the San Diego VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is: [redacted].

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Emily Treichler, PhD, is asking for your consent to this research. This study is being sponsored by the VA's Rehabilitation Research & Development service.

Emily Treichler, PhD is the developer of the therapy being studied in this research, Collaborative Decision Skills Training (CDST). No member of the research team has any significant financial interest or has any other conflict of interest related to this study.

By conducting this research project we hope to learn whether CDST, a group therapy, might help Veterans with serious mental illnesses who participate in care at the VA. CDST is a ten session, group based therapy that focuses on knowledge and skills that help people engage in treatment decision-making with their treatment teams. Previously, CDST has been tested among civilians with serious mental illness and with Veterans at CORE. In this study, we want to examine whether CDST is helpful for Veterans at CORE when compared with another group therapy: Goal-Focused Supportive Contact (GFSC). GFSC is also a ten session, group based therapy, but it focuses onsetting and achieving functional goals (e.g., living learning, working, and socializing). We will compare whether Veterans receive any benefits from CDST and GFSC, and whether there is any difference in the benefits they receive. We will also examine how to help VA clinics like CORE to use CDST on a regular basis, if it is effective.

You are being asked to participate because you participate in services at CORE. Approximately 72 people will take part in this research.

FOR HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately three years. Your individual participation in the project will take five months. This will include participating in ten group therapy sessions that will be held weekly at the Rio Clinic, and completing assessments at the beginning of the study, once you've finished your group, and three months after completing your group. We estimate that the total time you will spend on study activities will be approximately 20-25 hours.

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

1. First, you will complete two sets of assessments. These can be done on the same day or on separate days. Assessments will be completed virtually over phone or video or in person if physical distancing regulations allow it.
    a. The first assessment will be completing a set of measures with the help of a research staff member. These measures will capture areas including your current level of satisfaction with your treatment at CORE, your reasons for engaging in treatment, and your current sense of personal recovery. This assessment will take between 60-90 minutes.
    b. The second assessment will be a semi-structured interview. You will meet with Dr. Emily Treichler and another study staff member, who will ask you a set of questions about your experiences in treatment at CORE and outside of CORE. This interview will be audiotaped. This assessment will take about an hour.
    c. You will be able to skip any questions you would like. You will able to take breaks as needed during the assessment. If there are other things that would help you, please let the study staff know and we will do our best to accommodate you.
    d. Your answers will not be shared with the CORE treatment team or your other treatment providers. Your answers will not impact your services.
        i. The only exception is that if you report being at risk to yourself or others, we will discuss this with your treatment team to ensure your safety.
2. Up to eight of your appointments with your VA mental health providers will be audiotaped or videotaped during your participation in the study.
    a. Specifically, a maximum of two appointments will be audiotaped or videotaped at each stage of the study: 1) within a month before your group starts; 2) while your group is meeting; 3) within a month after your group ends; and 4) three months after your group ends.
    b. These appointments will be audiotaped or videotaped so that we can identify how you and your treatment providers make decisions and interact with each other.

   c. The audiotape or videotape from these appointments will only be used for research purposes and will not be shared with anyone outside of the study staff.
   d. Understanding how Veterans at CORE interact with their providers is key to our study. Therefore, you must agree to taping up to 8 of your appointments in order to participate.
3. You will be assigned to participate in either CDST or GFSC. Assignment is random, meaning that a computer will decide which group you participate in. This is because we want to make sure that the benefits you might get from participating in either CDST or GFSC are due to the group itself, not something else unique about you. Although those unique things are important too, they are not the focus of this study.
4. You will participate in ten sessions of either CDST or GFSC. Both groups will be held weekly for ten weeks. These groups will be structured very similarly as other groups you may have participated in at CORE. Groups will be virtual or in person if physical distancing regulations allow it and led by a CORE team member and supervised by Dr. Emily Treichler. Each group will be one hour long.
   a. There is one CDST group and one GFSC group. You may pick the time and day that works best for you.
   b. The CDST group will focus on topics including identifying members of your treatment team and what decisions you'd like each member to be involved in; thinking about treatment goals and treatment-related decisions that are important to you; learning ways to make decisions about treatment and how to work with other people to make those decisions; and navigating tough situations in your mental health care.
   c. The GFSC will focus on topics including psychoeducation, empathy, and non-directive reinforcement of health, coping, and symptom management behaviors.
   d. Like other groups at CORE, a progress note will be written by the group facilitator after each session and entered in CPRS.
   e. There will be at-home practice assigned after most sessions that you will complete between sessions.
5. After you have completed your group, you will complete two sets of assessments, which will be very similar to the ones you completed at the start of the study. As before, you can complete these on the same day or on separate days. These assessments will be completed over contact or video, or in person if physical distancing regulations allow it.
   a. The first assessment will be completing a set of measures with the help of a research staff member. These measures will capture areas including your current level of satisfaction with your treatment at CORE, your reasons for engaging in treatment, and your current sense of personal recovery. This assessment will take between 60-90 minutes.
   b. The second assessment will be a semi-structured interview. You will meet with Dr. Emily Treichler and another study staff member, who will ask you a set of

questions about your experience with CDST or GFSC and any changes you might have noticed since starting the study. This interview will be audiotaped. This assessment will take about an hour.

c. You will be able to skip any questions you would like. You will able to take breaks as needed during the assessment. If there are other things that would help you, please let the study staff know and we will do our best to accommodate you.
d. Your answers will not be shared with the CORE treatment team or your other treatment providers. Your answers will not impact your services.
    i. The only exception is that if you report being at risk to yourself or others, we will discuss this with your treatment team to ensure your safety.

6. If you are randomly assigned to CDST, you will have the option of completing a third assessment. If you choose to complete the third assessment, you will meet with Dr. Emily Treichler and another study staff member, who will ask you a set of questions about CDST and any changes you would recommend making to CDST to improve it. This interview will be audiotaped. This assessment will take about an hour.
    a. You will be able to skip any questions you would like. You will able to take breaks as needed during the assessment. If there are other things that would help you, please let the study staff know and we will do our best to accommodate you.
    b. Your answers will not be shared with the CORE treatment team or your other treatment providers. Your answers will not impact your services.
        i. The only exception is that if you report being at risk to yourself or others, we will discuss this with your treatment team to ensure your safety.
7. Three months after you complete CDST or GFSC, you will complete two sets of assessments, which will be very similar to the ones you completed at the start of the study. As before, you can complete these on the same day or on separate days. These assessments will be completed over phone or video, or in person if physical distancing regulations allow it.
    a. The first assessment will be completing a set of measures with the help of a research staff member. These measures will capture areas including your current level of satisfaction with your treatment at CORE, your reasons for engaging in treatment, and your current sense of personal recovery. This assessment will take between 60-90 minutes.
    b. The second assessment will be a semi-structured interview. You will meet with Dr. Emily Treichler and another study staff member, who will ask you a set of questions about your experience with CDST or GFSC and any changes you might have noticed since starting the study. This interview will be audiotaped. This assessment will take about an hour.
    c. You will be able to skip any questions you would like. You will able to take breaks as needed during the assessment. If there are other things that would help you, please let the study staff know and we will do our best to accommodate you.

   d. Your answers will not be shared with the CORE treatment team or your other treatment providers. Your answers will not impact your services.
      i. The only exception is that if you report being at risk to yourself or others, we will discuss this with your treatment team to ensure your safety.
8. If you have questions or concerns about the study, or would like to withdraw from the study, you may contact Dr. Emily Treichler or other study staff at any time. You may also discuss the study with your CORE providers or other VA providers.

If you participate, we expect that you will:

1. Attend your study appointments. If you need to miss an appointment, please contact the investigator or other research staff to reschedule as soon as you know you will miss the appointment.
2. Complete the assessments to the best of your ability.
3. Participate in CDST or GFSC to the best of your ability.
4. Ask questions and voice concerns as you think of them.
5. Tell the research staff or a CORE clinician if you feel like participating in the study is harmful for you.
6. Tell the study staff if you are currently participating in other studies or plan to participate in other studies while you are participating in this study.

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

All of the elements of this study are being done for research purposes.

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 may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Potential risks include: 1) emotional distress during the assessments or intervention due to discussing or thinking about emotional or uncomfortable topics; 2) short-term anxiety or discomfort due to attempting to change patient-provider dynamics if you participate in CDST; and 3)group therapies such as GFSC and CDST may be anxiety provoking due to being in a group setting with other participants..

There are no known medical, legal, or financial risks to participating in this study.

Although it is unlikely that this study will result in any significant negative psychological impact, the study staff will monitor your wellbeing throughout the study. We will also be in contact with CORE providers so that they can tell us if you seem to be struggling. If you are experiencing distress, we will talk to you about ways we can help, including referring you to services at CORE, elsewhere in the VA, or outside of the VA. We will decide whether continuing to participate in the study is in your best interests. Your safety, wellbeing, and preference will always be prioritized in these decisions.

You will always have the ability to decline to answer any question throughout data collection. You may ask for any accommodation that might help you and we will do our best to provide it as long as it is in our power and does not compromise study integrity. You may also decline to complete specific assessments, and may withdraw from the study at any time without any negative impacts on you or your ability to receive services at the VA.

There is always a chance that any procedure can harm you. The procedures in this study are no different. 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.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recordings to be made of you by the study team while you are participating in this study. You also authorize disclosure of the voice recording to Dr. Michelle Salyers, PhD, [redacted], and to Precision Transcription, LLC, 382 Lape Rd, Nassau, NY, 12123. The said voice recording is intended for the following purposes: 1) to understand how you and your treatment providers communicate; and 2) to record your responses to research questions.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and may rescind your consent for up to a reasonable time before the voice recording is used. Please understand that audio recording is a key part of our study, and therefore, if you decide not to be recorded now or in the future, you will also end your involvement with the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know whether you will benefit from participating in this study. However, possible benefits may include receiving a treatment from a skilled therapist. Participating in CDST may enhance your knowledge, skills and sense of personal recovery, leading to better interactions with your providers, improved wellbeing, and increased functioning. Participating in GFSC may improve your knowledge and skills related to setting and achieving functional goals.

This study also has the potential to benefit others. Specifically, CDST has the potential to improve the wellbeing and functioning of Veterans with serious mental illnesses by improving ability to succeed in mental health care, leading to better treatment engagement, higher treatment goal attainment, and better functioning in their day-to-day lives. If results of this and related studies indicate that CDST is effective, efforts will be made to make CDST available for all Veterans with serious mental illnesses receiving services at the San Diego VA and at other VAs. Similarly, GFSC has the potential to help Veterans set up and achieve functional goals. If GFSC shows evidence of being effective, efforts will be made to make GFSC available to all Veterans with serious mental illnesses receiving services at the San Diego VA and at other VAs.

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

Your alternative is not to participate. You will still have full access to all of the other CORE services, including all of the other groups being offered. You will not be able to participate in CDST or GFSC.

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 complete participation, the investigators will contact you to let you know these results.

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

There are no conceivable medical risks associated with this study. Still, 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 the research is conducted for VA under contract with an individual or non-VA institution. By signing this form, you do not give up any of your legal rights or release the VA from any liability.

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

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Principal Investigator: Emily Treichler, PhD

VA Facility: San Diego

DURING THE DAY (M-F, 8:00am-4:30pm):

Dr. Emily Treichler at [redacted]

IN URGENT MEDICAL SITUATIONS OR AFTER HOURS (night and weekends):

Call 911 or go to the nearest emergency room.

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 institution or loss of benefits to which you are entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The research team has the right to end your participation in the study in two situations:

1. If your health and wellbeing appears to be significantly and negatively impacted by being in the study. We know that your symptoms may change over time and may become worse during the study, and this alone will not cause us to terminate your participation. However, if we believe that participating in the study is causing you significant harm and that ending the study would help you, we have the right to terminate your participation.
2. If your actions present a risk to other Veterans in the study, to study staff, or to other VA staff. If you act in an aggressive or threatening manner towards other Veterans or VA staff, we will terminate your participation.

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

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 that are not part of this study. If you receive a bill for a service that is a part of the study, please contact Dr. Emily Treichler at [redacted]

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

The two major assessments are the semi-structured interviews and the quantitative assessments. You will be compensated $25 for the semi-structured interviews and $40 for the quantitative assessments. This includes two assessments before CDST/GFSC starts, two

assessments right after CDST/GFSC ends, and two assessments three months after CDST/GFSC ends. That means that if you completed all six (6) assessments, you would receive total compensation of $195.

Additionally, for CDST participants who choose to complete the third assessment right after CDST ends will receive an additional $25.

All compensation will be paid in cash and given to you on the day you complete each assessment. You will still receive the full amount if you decline to answer specific questions. You may complete assessments and receive full compensation regardless of your level of participation in past assessment or in CDST/GFSC. If you withdraw from the study, you won't receive any further compensation.

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 Dr. Emily Treichler at [redacted]

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 [redacted], VA Research Service at [redacted], VA Regional Counsel at [redacted], or the VASDHS Institutional Review Board at [redacted]. This is the Board that is responsible for overseeing the safety of human participants in this study.

FUTURE USE OF DATA AND RE-CONTACT

The study team would like your approval to contact you in the future about other research studies that you might want to participant in. If you approve, we will keep your name and phone number on file for future studies that are led by Dr. Emily Treichler at the VA San Diego. You would only be contacted by Dr. Emily Treichler or one of her study team members. Your information would not be shared outside of Dr. Emily Treichler's study team. You would only be contacted for mental health focused research that you might be eligible for.

☐ **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 PRIVATE INFORMATION BE PROTECTED?

All data will be collected for research purposes and treated in a confidential manner. Loss of confidentiality is a risk of participating in research, although it is rare given appropriate procedures. There is a very small risk that sensitive information (like diagnosis) could become known outside the research setting. We will take significant efforts to protect all research data and keep this risk low. Our efforts include: keeping identifiable data (like your name) in separate files from the rest of the data; limiting access to data so that only people who need to have access (like a study staff member) are able to access the data and electronically protecting files and storing them on the VA hard drive. 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.

We will include information about your study participation in your medical record. Progress notes regarding your participation in the CDST/GFSC sessions will be documented in CPRS by the group facilitator. These notes will be available to other CORE treatment team members. Notes will not be entered for any assessment appointment.

Mandated reporting laws and policies apply to your interactions with study staff and clinicians associated with this study. Therefore, we are mandated to report if you 1) report being at risk to yourself or others; or 2) report knowledge of a minor child or vulnerable adult being abused.

While this study is being conducted you will have access to your research related health records.

Combined data will be analyzed here at the VA as well as at Colorado State University, where Dr. Michael Thomas, a consultant on the project, currently works as a professor. Dr. Thomas and all other non-VA staff who work with data from this project will receive only coded data and will not receive the list that matches your name to your code number.

Identifiers might be removed from the identifiable private information that are collected. After that removal, 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.

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

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

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Principal Investigator: Emily Treichler, PhD

VA Facility: San Diego

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.

Dr. Emily Treichler and/or another research staff member 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. A copy of this signed consent will also be put in my medical record.

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

_____ _____
Participant's Signature Date

_____ _____
Or Signature of Legally Authorized Representative Legally Authorized Representative (print)

_____ _____ _____
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 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 your mental health treatment records.

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, 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.

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.

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, the 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.

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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. A copy of this signed document will also be put in my medical record.

Participant's Signature	Last 4 of SSN	Date

Signature of Legally Authorized Representative	Date

Legally Authorized Representative (print)

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 ([redacted] or [redacted]. You may leave an anonymous comment at the VASDHS research compliance hotline at 8[redacted].

REF: California HSC 24170-24179.5

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