Suvorexant: A Dual Orexin Receptor Antagonist for Treating Sleep Disturbance in Posttraumatic Stress

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Department of Veterans Affairs	**INFORMED CONSENT FORM**
Subject Name:	**Date:**
Title of Study: Suvorexant: A Dual Orexin Receptor Antagonist for Treating Sleep Disturbance in Posttraumatic Stress	
Principal Investigator: Sabra Inslicht, Ph.D.	**San Francisco VA Health Care System**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a research study to test the safety and effectiveness of an experimental drug for sleep disturbance in individuals with post-traumatic stress disorder (PTS), Suvorexant. This drug is marketed under the brand name: Belsomra. You have been asked to take part in this study because you have symptoms of sleep disturbance and PTS. The Principal Investigator for this study is Sabra Inslicht Ph.D., from the San Francisco Veterans Affairs Health Care Center (SFVAHCS). A member from the research team will explain this study to you.

Research studies only include people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family, your friends, and your health care team. If you have any questions, you may ask someone from the study team.

You are being asked to take part in this study because you state you have experienced a highly stressful event and believe you have Posttraumatic Stress and/or because you have trouble sleeping.

WHY IS THIS STUDY BEING DONE?

Disturbed sleep is the most prevalent symptom reported by patients with PTS. Suvorexant is an FDA approved medication for the treatment of sleep disturbance. The purpose of this study is to test the effects of the medication Suvorexant on symptoms of sleep disturbance and PTS, in comparison to Placebo (an inactive substance), in Servicemembers and Veterans.

This study is being funded by the Department of Veterans Affairs.
Study location: Blood draws, urine samples, and pregnancy tests will be performed at all the following locations: VA Heath Care Center, Zuckerburg SF General Hospital, UCSF Parnassus Hospital, and Quest Diagnostics. All other procedures and tests will take place at the San Francisco VA Health Care Center.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 72 Veterans will take part in the study at the SFVAHCS. In addition, 72 Veterans will take part in the study at other VA medical centers.

10 additional individuals will be recruited to pilot test a remote fear conditioning task.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree, the following procedures will occur:

The entire study will last for approximately 16 weeks. After 2 weeks of screening and preliminary testing, you will be randomly assigned to one of two treatment groups: Suvorexant or Placebo (an inactive substance). You will take your assigned treatment for 12 weeks, and study staff will follow up with you after you stop treatment. All study procedures are described in detail below.

1) **Eligibility Assessments:** You will need to have the following "screening" exams, tests or procedures to determine if you can participate in the main part of the study.
   - **Clinical Interview:** A research mental health clinician will ask you questions about your mental health, including questions your mental health history and alcohol and drug use. This assessment will be audio-taped to ensure that all study clinicians are following standardized assessment procedures. This assessment will also be videotaped to measure your physical reactivity (heart rate) to the interview by applying specialized computer software. Audiotapes will be kept in secure, locked cabinets within locked offices. Video recordings will be kept on the protected San Francisco VA Medical Center network storage. Once the video is collected, any link between your identifying information and your data will be destroyed. You will have the option to opt out of being video recorded and this will have no impact on your participation. Only the study investigators and study staff will have access to these audiotapes and video recordings. They will be stored for the duration of the study and as required by VA policy.
   - **Sleep Apnea Screen**: You will be screened (evaluated) for obstructive sleep apnea, a breathing condition which affects people's ability to sleep. This screening evaluation involves wearing an oximeter on your finger and another small device that assesses your breathing while you sleep for one night. It is a painless, noninvasive procedure. If you screen positive, study staff will ask your permission to share the results with a VA medical provider so you can get treatment for obstructive sleep apnea prior to continuing with study screening.
   - **Medical Screen:** You will meet with a research team member who will ask you questions about your medical history, current health, medications, and sleep patterns. Vital signs, height, and weight will be assessed, and a brief physical exam will be performed. Urine and blood samples will be collected (see details below). This process will take about 1 hour.
   - **Urine Sample**: You will be asked to give a urine sample for laboratory tests to screen for drugs of abuse. This test is for screening purposes only to ensure that you are eligible to participate in the study. You must have a negative urine toxicology screen to participate in the study. If you screen positive on the drugs of abuse screen, you will be counseled about the results by a mental health clinician and referrals for substance abuse treatment may be provided. Urine samples will be provided at any of the following locations: SF VA Health Care System, Zuckerberg SF General Hospital, UCSF Parnassus hospital, or Quest Diagnostics Clinics. Quest Diagnostics Clinics will be used only in the case when you are unable to travel to any location listed within SF.
   - **Blood Draw (venipuncture):** You will be asked to give a blood sample for laboratory tests to look for evidence of medical illness. Approximately 15 ml (1 tablespoon) of blood will be drawn by inserting a needle into a vein in your arm. The blood test is performed to ensure that no health complications will occur as a result of your study participation. Studies performed include complete blood count, liver function test, blood electrolytes, and thyroid function tests. In the event of abnormal screening test results, you will be counseled about these by the study physician, referred for medical treatments as appropriate, and with your permission, we will share lab results with your VA provider. Blood draws will either occur at the SF VA Health Care System, Zuckerberg SF General Hospital, UCSF Parnassus hospital, or Quest Diagnostics Clinics. Quest Diagnostics Clinics will be used only in the case when you are unable to travel to any location listed within SF.
   - **Pregnancy Testing:** Because we do not know for sure that Suvorexant is safe for fetuses, pregnant women may not participate in this study. If you are a woman able to bear children, you must have a negative pregnancy test as part of the screening procedures. If you become pregnant while in this study, you will immediately contact the study physician and will be counseled as to your possible alternatives. If you are a man or a woman and engage in heterosexual intercourse, you must be willing to practice appropriate birth control or abstain from sex for the duration of the study. Pregnancy tests will be performed at any of the following locations: SF VA Health Care System, Zuckerberg SF General Hospital, UCSF Parnassus hospital, or Quest Diagnostics Clinics.

- **OPTIONAL COMPONENT:**
  Blood and Saliva Banking for Future Research Including Genetic Testing: Scientists do not fully understand the relationship between biology, genetics, other biological markers, and many conditions, including PTSD. An extension of this study will involve collecting and storing samples of your blood for future research, including genetic analyses. You may select which, if any, of the biological samples you would like to give permission for the study to collect and store for future research. The samples may eventually be analyzed for genetic information, hormones, immune function indicators, and other biomarkers.

  If you choose to participate in any of these optional procedures, the following will happen:
  - **Blood Sample:** An additional 4 tablespoons (57 ml) of blood will be drawn during V0 (Baseline visit), V4 (Week 8), and V5 (End of Treatment) and stored in a secure freezer at the SFVAHCS for future research. Any specimens left over from the other blood draws may also be stored in the same manner.
  - **Saliva Sample:** You will be asked to provide saliva samples during V0 (Baseline). A research assistant will provide you with a saliva collection kit and instructions for collecting the sample. The samples will be stored with a study ID code and stored in a secure freezer at the SFVAHCS.

  Your biological samples will be stored in a secure lab at the SFVAHCS. We do not know for sure if your specimens will be used, but they might be used in research about PTSD or other conditions. Your samples may eventually be shipped outside the VA for analysis. Your samples will be stored for as long as possible, and may be used to perform many tests, including genetic analysis, and analysis for other biomarkers. Your samples and other research information will be labeled with a code number, not your name. Biological information taken from the specimens may be shared broadly in coded form. No identifying information will be shared or published.

  Your specimens will be kept indefinitely. You will always have the right to have your samples destroyed at any time by contacting Dr. Inslicht at 415-221-4810 x23341 or Dr. Neylan at (415) 750-6961. Although samples are stored without your name, the research team can use your study ID to locate and destroy the samples. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

If the mental health assessment, screening exams, and lab tests show that you can continue to be in the study, and you choose to take part, you will be required to register and have an open medical chart at the San Francisco Veterans Affairs Health Care System if you do not already have a VA medical record.

2) **Pre-Treatment Assessments**: Before you begin the Suvorexant treatment or Placebo, the following procedures to monitor and measure your sleep and wake patterns will be completed in the week prior.
   - **Questionnaires:** You will be asked to complete a set of questionnaires about mental health symptoms you may experience, and about your sleep quality and life satisfaction. This set of questionnaires will take about 30 minutes to complete.
   - **Sleep Diary**: You will complete either an electronic or paper sleep diary every evening and morning for 7 days. Each evening you will record how much, if any, caffeine, alcohol and/or medications you took as well as how fatigued you were feeling that day and document experiences of stress and naps taken during the day. Each morning you will record your estimated sleep time, and the number of times you woke after bedtime. The diary takes approximately 5 minutes total to complete each evening and morning.

- **Activity Monitor:** You will wear a monitoring device, called an actigraph, that will measure your wrist movement during waking and sleep. You will wear this device on your wrist, like a watch, at all times. In addition, we will also send you home with a Sleep Profiler which is a device worn on the forehead like a headband. We will ask that you wear the Sleep Profiler for three nights prior to your V1 (Start of Treatment Visit).
- **Clinical Interview:** If 30 days have elapsed since your last clinical interview, a research mental health clinician will ask you questions about your mental health, including questions about your mental health history (from the past week and past month) and alcohol and drug use. This assessment will be audiotaped to ensure that all study clinicians are following standardized assessment procedures. Interviews will be recorded on digital audiotape. The audiotaped interview will be encrypted and passcode-protected while stored on a secure VA web server and may be reviewed by other study team members. Only the study investigators and study staff will have access to these audiotapes. They will be stored for the duration of the study and as required by VA policy.

3) Treatment: After completing the above procedures, you will then begin the treatment phase of your participation. All tasks are described below:

- **Randomization:** You will be randomized into one of two study drug groups. Randomization means that you are put into a group by chance. A computer program will place you into one of the groups. Neither you nor anyone from the study team can choose the group that you will be in. You will have an equal chance of being placed in either the Suvorexant or Placebo group. Neither you nor the research staff will know which drug group has been assigned to you.
- **Study Drug Treatment Visits:** You will meet, or have a call, with a study doctor at weeks 1, 2, 4, 8, 12, and 13. The doctor will prescribe the lowest medication dosage and instruct you to take the medication nightly 30 minutes before you go to sleep and at least 7 hours before you need to wake up. You will be given Suvorexant or an identical Placebo from the VAMC pharmacy in a counted tablet bottle, so that medication compliance can be monitored. The study doctor, or study staff, will count your pills at each visit. Should you have any questions or concerns regarding the medication, you will be given a wallet card that provides emergency contact numbers of the study physicians.
    - **Study drug dose changes ("titration phase"):** At the first visit, you will be started on a low dose to be taken 30 minutes before bedtime. During the first 2 weeks, your study doctor will call you after one and two weeks to discuss any medication effects and determine whether or not the dose should be adjusted. If you are tolerating the medication well and are still experiencing PTS or sleep difficulties, the dose will be increased. This gradual increase in the dose is referred to as titration. The decision to decrease or increase your medication will depend on whether you are experiencing any side-effects and whether you are still experiencing PTS and sleep problems. The maximum dose of Suvorexant that you could be prescribed is 20mg daily.
    - **Stable-dose study drug treatment:** After 2 weeks of titration, you will continue to take the study drug at a stable dose (no more dose increases will occur) for an additional 10 weeks. You will meet with your study clinician 3 times during that 10-week period.
- **Questionnaires:** At your Baseline visit and at weeks 1, 2, 4, 8, 12, & 13 you will be asked to complete a set of questionnaires, which include questions about mental health symptoms you may experience and about your sleep quality and life satisfaction. Several questionnaires will also be administered by phone, during the phone call with the study doctor. This set of questionnaires will take about 30 minutes to complete.

- **Clinical Interview:** A research mental health clinician will ask you questions about your mental health at weeks 4, 8, and 12, and these will include questions your mental health history (from the past week or past month) and alcohol and drug use. This assessment will be audiotaped to ensure that all study clinicians are following standardized assessment procedures. This assessment will also be videotaped to measure your physical reactivity (heart rate) to the interview by applying specialized computer software. Audiotapes will be kept in secure, locked cabinets within locked offices. Video recordings will be kept on the protected San Francisco VA Medical Center network storage. Once the video is collected, any link between your identifying information and your data will be destroyed. You will have the option to opt out of being video recorded, and this will have no impact on your participation. Only the study investigators and study staff will have access to these audiotapes and video recordings. They will be stored for the duration of the study and as required by VA policy.
- **Sleep Diary**: You will complete an electronic or paper sleep diary every evening and morning. Each evening you will record how much, if any, caffeine, alcohol and/or medications you took as well as how fatigued you were feeling that day and document experiences of stress and naps taken during the day. Each morning you will record your estimated sleep time, and the number of times you woke after bedtime. The diary takes approximately 5 minutes total to complete each evening and morning.
- **Activity Monitor:** You will wear a monitoring device, called an actigraph, that will measure your wrist movement during waking and sleep. You will wear this device on your wrist, like a watch, at all times for the duration of the treatment. In addition, we will also send you home with a Sleep Profiler which is a device worn on the forehead like a head band for three nights. We will also ask that you wear the Sleep Profiler for three nights prior to your V4 and V5 treatment visits.
- **Baseline and Trauma Challenge Psychophysiology Recording:** Participants will be informed that they may discontinue the assessment at any time. The procedure includes a Baseline phase and a Trauma Challenge (trauma interview and trauma imagery) phase. During the baseline phase, skin conductance and heart rate are monitored continuously with the Empatica E4watch or Esense sensors for 5 minutes while the participant rests quietly without talking. These devices certified CE device designed to measure physiology unobtrusively. During the first part of the Trauma Challenge, heart rate and skin conductance are continuously measured while the participant is administered a 21-question, open-ended trauma interview. After the interview, skin conductance and heart rate are monitored continuously for 60 seconds while the participant is asked to think about and imagine the traumatic event.
- **Random Drug Testing:** At two random time points throughout your study participation, you will be asked to provide a urine sample, which will be used for drug testing. This random drug test is requested to ensure that neither your health nor the medication effectiveness is compromised by any prescribed or recreational drug(s).
- **Post-Treatment/Rebound Study Visit:** On week 13, you will meet with a study clinician who will ask you questions about your mental health, including questions about posttraumatic stress (PTS), and any sleep difficulties. You will be asked to monitor your sleep for two (2) days and nights using the mobile actigraph wristband and sleep diary as outlined under the "Activity Monitor & Sleep Diary" sections. For further care after you complete the study, the study doctor will refer you back to your primary care physician or provide you with a referral to a clinic in your community.
- **OPTIONAL COMPONENT:**

  Fear Conditioning Tasks: We will examine how anticipation of an electric stimulus on your fingers and/or an auditory stimulus affects your body's response to visual images. You will watch colored circles on a computer monitor, sometimes while receiving a mild electric or auditory stimulus, and sometimes with no stimulus. Your body's responses will be measured in a few ways: heart rate, respiration, sweat gland activity, eye blink/forehead movement, and eye movement. Your heart rate will be measured using sensors taped to your torso. Your respiration will be measuring using a band strapped around your torso with a sensor attached. Your sweat gland activity will be measured using two small sensors attached to

your hand. Your eye blink/forehead response will be measured with two sensors taped above your left eyebrow and/or under your eye and a third one placed on your forehead. You will not receive any electrical stimuli from these sensors. Their only purpose is to measure heart rate, respiration, sweat gland activity, and eye blink/forehead movement. Your eye movement will be measured by a camera placed in front of you. You may be asked to complete a breathalyzer test prior to the fear conditioning task. Additionally, you may be videotaped to complete a photoplethysmography during the task by applying specialized computer software. The only required equipment to complete the photoplethysmography will be to have an at-home device with videorecording functionality, which, if not available, will be provided and mailed accordingly. Following the completion of the task, video recording equipment will be returned through mail following study staff provided instructions. Once collected, video recordings will be kept on the protected San Francisco VA Medical Center network storage. Once the video is collected, any link between your identifying information and your data will be destroyed. You will have the option to opt out of being video recorded. At the end of the conditioning sessions, you will be asked to answer questions about the experiment. This procedure will take up to 1 hour and will take place at V1 (Baseline) and V5 (End of Treatment). Versions of this task may be administered in lab or at the participant's home.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for a total of 16 consecutive weeks. Please see below for a timetable describing the stages and duration of the study.

	Time Commitment (hrs)	**Payment**** **Where applicable, payment occurs after study completion and return of all equipment.
Recruitment & Phone Screening	0:30	$0
Informed Consent	0:30	$0
Phone Eligibility Assessment		
Clinical Interview	3:00	$45
Medical Eligibility: Visit 0		
*If needed, In-Home Sleep Apnea Screening	*4:15	$0
Labwork (Blood and saliva sample collection optional)	0:10	$10
1-week Actigraphy and Sleep Monitoring	0:35	$30
Baseline/Week 1: Visit 1		
In person NP/MD Medication Start	0:30	$10
Self-report Questionnaires	0:30	$10
Fear Conditioning Tasks (optional)	1:00	$15
Baseline and Trauma Challenge Psychophysiology Recording	0:20	$10
Week 2: Visit 2		
Study Appointment	0:30	$10
Self-Report Questionnaires	0:30	$10

Week 4: Visit 3		
Study Appointment	0:30	$10
Self-Report Questionnaires	0:30	$10
1-week Actigraphy and Sleep Monitoring	0:35	$30
Clinical Interview	1:00	$25
Week 8: Visit 4		
Study Appointment	0:30	$10
Self-Report Questionnaires	0:30	$10
1-week Actigraphy and Sleep Monitoring	0:35	$30
Labwork (Blood sample collection optional)	0:10	$10
Clinical Interview	1:00	$25
Week 12/End of Treatment: Visit 5		
Study Appointment	0:30	$10
Self-Report Questionnaires	0:30	$10
1-week Actigraphy and Sleep Monitoring	0:35	$30
Clinical Interview	1:00	$25
Fear Conditioning Tasks (optional)	1:00	$15
Baseline and Trauma Challenge Psychophysiology Recording	0:20	$10
Labwork (Blood sample collection optional)	0:10	$10
Week 13/Rebound: Visit 6		
Study Appointment	0:30	$10
Self-Report Questionnaires	0:30	$10
2-night Actigraphy and Sleep Monitoring	0:35	$10
Bonus for Completing		$50
	19:05(*23:20)	**$500**

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

In return for your time and effort, you will be reimbursed according to the chart above.

Based on these rates, you may receive up to $500. You will be reimbursed for each portion of the study that you finish, regardless of whether or not you complete the study. Payment will be by direct deposit as preferred by the Department of Veterans Affairs. Each participant will need to provide their social security number for payment to be processed, as well as bank account number and routing number for Direct Deposit. You will be paid at the end of your participation in the study and when all equipment has been returned.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study clinician if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. It is important to tell the study doctor if you are thinking about stopping so that your clinician can evaluate any risks and discuss what alternative follow-up care and testing could be most helpful for you.

The study clinician may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped. You will not lose any of your regular benefits, and you can still receive your care from our institution the way you usually do.

Also, the study researcher may withdraw you from the study at any time if we believe it is in your best interest or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

You may have side effects while in the study. Everyone taking part in the study will be watched carefullyfor any side effects. However, clinicians don't know all the side effects that may happen. Side effects maybe mild or very serious. You should talk to your study clinician about any side effects that you experiencewhile taking part in the study.

Risks and side effects related to taking Suvorexant include those which are: The most frequent reactions associated with Suvorexant therapy are as follows:

- sleepiness (7%)
- headache (7%)
- dizziness (3%)
- diarrhea (2%)
- dry mouth (2%)
- upper respiratory tract infection (2%)
- abnormal dreams (2%)
- cough (2%)

(Percentage of people who report this side-effect in those using Suvorexant)

For more information about risks, please ask one of the researchers. We can provide you with the medication guide for full details.

During the medical screening and evaluation, the study clinician will ask questions to determine if you might be at higher risk for one of these serious adverse events. Should you experience any side-effects while on study medication, your study physician/nurse practitioner will work closely with you to make decisions about dose changes, and whether it is safe to continue in the study. You will be free to end your participation at any time if you find side effects intolerable.

Clinical Interview: You will be asked to discuss psychological symptoms and potentially sensitive topics. It is possible that you may experience varying degrees of emotional discomfort. However, in most cases, we do not foresee individuals having prolonged discomfort due to study participation. If you feel uncomfortable, you may decline to answer any questions and/or to stop participating in the study at any time. If, for any reason, you experience significant distress, we will conduct a thorough assessment and help you receive necessary care and/or connect with your mental health provider. If you are not currently connected with mental health services, we can assist with a referral.

Activity Monitor: There is no risk of injury from wearing the activity monitor (actigraph) or Sleep Profiler. You may find it annoying to have to wear. You may stop wearing the actigraph or Sleep Profiler if you choose and this will not affect your continued participation in this study.

Fear Conditioning Tasks: There are no serious risks associated with the conditioning task. Before the experiment starts, you will be asked to choose your own level of electrical stimulus that is highly annoying but not painful. The electrical stimulus is mild (0.2- 4.0 mA) and 5 milliseconds in duration, which is not harmful. It is possible that you may have strong feelings of anxiety and discomfort during the testing. Should you want to stop the testing you may do so at any time. The test has been used in several studies of people with PTSD and there are no known risks, although it has not been used as extensively with people who were recently traumatized. The electrodes used to measure your reactions during the tests can sometimes cause skin irritation. The infrared camera can cause dry eyes but meets IEC standards for eye safety.

Baseline and Trauma Challenge Psychophysiology Recording: You will be asked to discuss psychological symptoms and potentially sensitive topics. It is possible that you may experience varying degrees of emotional discomfort. However, in most cases, we do not foresee individuals having prolonged discomfort due to study participation. If you feel uncomfortable, you may decline to answer any questions and/or to stop participating in the study at any time. If, for any reason, you experience significant distress, we will conduct a thorough assessment and help you receive necessary care and/or connect with your mental health provider. If you are not currently connected with mental health services, we can assist with a referral. You will be asked to wear the Empatica E4 watch or Esense sensors during the assessment. There is no risk of injury from wearing the device. You may stop wearing the E4 device or Esense sensors at any time. If you choose to stop wearing the device, this will not impact your continued participation in this study.

Blood drawing (venipuncture) risks: Drawing blood may cause temporary discomfort from the needle stick, bruising, and infection.

Reproductive risks: You should not become pregnant while in this study. Risks to a fetus and sperm are not known. Since the risks have not been adequately studied and therefore are not well known, you will be asked to practice appropriate birth control or abstain from sex for the duration of the study. Appropriate birth control methods include condoms, oral contraceptives, IUD, birth control patch or ring. If you become pregnant while in the study, we will have to end your participation in the study and your treatment with Suvorexant. You will be counseled about possible alternative treatments.

Unknown Risks: The experimental treatments may have side effects that have not come to the attention of researchers or the FDA. The researchers will inform you if any new findings on the study drug suggest that you should stop the medication intervention.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may or may not result in improvements in PTS and/or sleep disturbance. Your participation in any part of the study contributes to medical knowledge related to the treatment of PTS and sleep disturbance. Your participation may lead to knowledge that can be used to improve healthcare for other Veterans.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You are free to choose not to participate in the study. You will not lose any of your regular benefits, and you can still get care from our institution the way you usually do.

Alternative options might include:

- Getting a different experimental treatment/taking part in another study
- Consulting with your primary care physician about standard pharmaceutical or behavioral therapies for your condition without being in a study

As a veteran, you are eligible for services at the VA Medical Center and your study clinician can help you access appropriate treatment at the medical center.

HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?

Your study records will be kept as confidential as is possible under the law. However, we cannot guarantee total privacy. Your personal information may be given out if required by law, for instance, if it were learned through the research study that you were a danger to yourself or others (i.e., you are suicidal, homicidal and have a specific plan, or if you disclose that a child or dependent adult is being abused). The appropriate authorities would be notified, as required by law. If you are being seen in mental health treatment at the SFVAHCS and express suicidal feelings, we will contact your provider so that he/she is aware and can contact you for assistance. In this study, you will be tested for drug use. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, research records have been subpoenaed by a court.

Other study information, such as the interviews, questionnaires and bio-specimens, will be coded with a code number unique to the study. Only research study personnel, with the permission of the principal investigator, will have access to the files with the name and ID codes. If information from this study is published or presented at scientific meetings, your name and other personal information will never be used.

If you don't already have one, a medical record will be created because of your participation in this study. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)
- The Department of Veterans Affairs

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. Researchers may make disclosures if they become aware of the following: a) that you intend to harm yourself or someone else, b) that a child had been abused or neglected, or c) that an elder

or dependent had been abused. Should this happen, the appropriate authorities (i.e., your primaryor mental health provider, emergency respondents, or local police) would be notified. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

WILL MY PICTURE OR VOICE BE RECORDED?

Your initial assessment interview and treatments will be audio-recorded in order to make sure that the assessments and treatments are delivered in the appropriate manner. Recordings will be removed from recorder devices and stored securely at the San Francisco VA Medical Center. These assessments and the fear conditioning task will also be videotaped to measure your physical reactivity (heart rate) to the interview and task by applying specialized computer software. Audiotapes will be kept in secure, locked cabinets within locked offices. Video recordings will be kept on the protected San Francisco VA Medical Center network storage. Once the video is collected, any link between your identifying information and your data will be destroyed. You will have the option to opt out of being video recorded and this will have no impact on your participation. These recordings will be used for research purposes only and will not be disclosed outside of the research team.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no costs for taking part in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

Treatment and Compensation for Injury: If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable) or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided. It is important that you tell the Principal Investigator, Dr. Sabra Inslicht, if you feel that you have been injured because of taking part in this study. You can tell the researcher in person or contact her at (415) 221-4810 ext. 23341

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get care from our institution the way you usually do.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to the researcher or research staff about any questions, concerns, or complaints you have about this study. You may contact the Principal Investigator Dr. Sabra Inslicht at (415) 221-4810 ext. 23341 or the research coordinator at (415) 221-4810 ext. 22752.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at (415) 476-1814. 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.

COMMITMENT TO DIVERSITY

This study is part of the Stress and Health Research Program which welcomes all people, regardless of race, ethnicity, culture, physical appearance, ability, age, gender, gender identity, sexual orientation, political view, and religion. We strive to create a shared research environment of mutual respect and acceptance for you and all our study staff.

To this end, we expect participants to engage in a shared agreement with study staff to not make any negative comments about race, ethnicity, physical appearance, ability, age, culture, gender, gender identity, sexual orientation, political views and religion. This agreement also extends to sexual harassment, which includes sexual advances, requests for sexual favors, or other verbal, written, physical, or visual conduct of a sexual nature. Respect is essential for maintaining a productive research environment that is welcoming to everyone.

Study staff will bring up concerns about harmful language and behavior to you and/or the study researchers. The study researchers may stop you from taking part in this study at any time if they believe it is in your best interest or if you do not follow study rules.

CONSENT

You will be given a copy of this consent form and the Experimental Subject's Bill of Rights to keep.
You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

_____By initialing, you authorize the use of digital audio recordings of the interview for review by research team members (required for study participation).

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent

(Consent for optional procedures on next page)

CONSENT TO PARTICIPATE IN OPTIONAL STUDY PROCEDURES

Please write your **INITIALS** on the appropriate line:

BIOLOGICAL SPECIMEN COLLECTION AND BANKING (optional):

I agree to provide the following biological samples and authorize them to be stored and banked for future research.

Blood: YES_____ NO_____

Saliva: YES_____ NO_____

VIDEO RECORDING (optional):

I agree to be video recorded during study tasks and authorize the recorded files to be securely stored for future research.

Video: YES_____ NO_____

FEAR CONDITIONING TASKS (optional):

I agree to complete the fear conditioning tasks.

Fear conditioning tasks: YES_____ NO_____

CONTACT FOR FUTURE RESEARCH (optional):

Someone may contact me in the future to ask me to take part in future research:

Future research: YES_____ NO_____