

STUDY INFORMATION SHEET

PLEASE KEEP THIS DOCUMENT FOR FUTURE REFERENCE

Genomics of Posttraumatic Stress Disorder in Veterans

VA Cooperative Studies Program Study #575B

Study Chairs: Joel E. Gelernter and Murray B. Stein

Introduction:

You are being invited to take part in a research project that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done, what procedures it will involve, any potential risks to you and any potential benefits you may receive.

Read the information below closely, and discuss it with family and friends if you wish. A study team member from the San Diego VA will contact you to review this document with you and answer any questions. In the meantime, if there is anything that is not clear or if you would like more details about this research, you are encouraged to contact a member of the study team toll free at 1-844-343-0678.

BACKGROUND AND PURPOSE

The long-term goal of the research project is to identify genes that contribute to or protect against developing stress reactions. Combat and other stress reactions can occur after someone has seen or experienced a life-threatening traumatic event. Individuals who have stress reactions may have trouble sleeping, trouble relaxing or concentrating, and may have recurrent thoughts and memories about their trauma.

Most human diseases have an inherited element. Inherited traits are passed down from one generation to the next in DNA, the genetic material. We hope to learn about how genetic make-up/DNA found in the blood relates to stress reactions and other illnesses and behaviors that can occur in military personnel. Furthermore, we hope to learn about how genes and the other materials we find in your blood relate to other illnesses and behaviors and things you told us about as being part of the Million Veteran Program (MVP).

The immediate goal is to scientifically measure PTSD symptoms in Veterans who have served in combat. We will accomplish this by conducting a telephone interview with randomly selected sample of 400 Veterans who were exposed to combat and are part of the Million Veteran Program (MVP). You are one of the Vets who has been selected and invited to participate.

The phone interview itself uses a questionnaire that is considered the “gold standard” for assessing PTSD. It takes on average about 60 minutes, depending on your responses and your availability. We are asking Veterans being interviewed to allow us to audiotape the phone interview. The purpose of that is to make sure that the interviewer is asking the questions the right way. We will then randomly select 10% of the audio recordings (40 interviews) and have another interviewer who is part of this study listen to the recordings.

We will also send some of the recordings to an author of the questions, to ensure that interviewers have followed guidelines outlined in the study. You do not have to agree to be recorded in order to participate but it will help us out. Finally, you will receive \$50 for your time via an Electronic Fund Transfer or via check.

As mentioned, your participation will take, on average, about one hour over the telephone. We are interviewing about 400 Vets and that will take about 1 year. The larger study will take about 3 years.

What will happen to you: We will ask you questions about your military history, deployment experiences, mood, and stress symptoms that you may or may not have. All questions are for research purposes only. We will also ask you for your contact and other information so that we can process your payment.

Risks (reasonably) to be expected: Participation in this study may involve some added discomforts. There are no expected serious risks to your emotional or physical health associated with being in the study. However, you might feel emotionally distressed from revealing personal information or discussing your war experiences during the interview and survey questions. Some of the telephone interview questions are of a sensitive nature and may make you feel uncomfortable, though we have tried to make the process as comfortable as possible. If you feel upset during the interview, you may stop or take a break. If you feel upset and would like to speak with a medical or mental health professional at any point during the interview, we can stay on the line and transfer you to speak with someone at the Veterans Crisis Line at 1-800-273-TALK (8255). You may also discuss what you are feeling with your interviewer, who may have the study psychiatrist contact you, if needed. Sometimes emotional distress can happen several days after the interview. If you become distressed, please either call the Veterans Crisis Line or go to your local VA medical center's psychiatric emergency clinic for assistance. If you so choose, you are free to skip or not answer questions from any or all parts of the study without penalty or prejudice. As a reminder, the Veterans Crisis Line is available 24 hours a day, 7 days a week. You can call the number toll free at 1-800-273-TALK (8255) and press 1, send a text message to 838255, or use the Veterans Chat Line at www.suicidepreventionlifeline.org at any time you need to speak with someone.

To reduce inconvenience to you in taking part in this study, we will make every effort to allow you to select interview times that work best for you. These will include regular business hours, evenings, and weekends. The telephone interview will take on average about 60 minutes to complete, which may make you feel tired. However, you may ask the interviewer for a break at any time during the interview.

Privacy and Confidentiality: Taking part in this study will involve the project collecting private information about you, but this information will be handled as confidentially as possible. Information collected for the purpose of this research study will be kept confidential as required by law. The results of the research may be published in scientific papers, but your name will not be used and your records and identity will not be revealed unless required by law. Your data will be combined with data from other people taking

part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not personally identify you. Study codes will be used for study reports to help maintain participant confidentiality.

Please be aware that there are certain limits to confidentiality. If you express suicidal or homicidal intent, we will notify healthcare professionals, law enforcement officials, and family members/significant others, as appropriate, to protect you and others. We are also obliged to warn anyone you have expressed the intent to harm. There is also the chance that we will need to contact you and/or your family member after your participation in the study if we are concerned about your safety. While complete confidentiality cannot be guaranteed, all personal information collected will be kept confidential as required by law.

Information about you is protected in the following ways:

- Every effort will be made to make sure that the information about you that we gather as part of this study will be kept strictly confidential. Only approved VA staff will know your identity.
- We will follow standard research procedures that require any private information that could identify you such as your name, address, past medical history, and social security number, to be kept separate (either in locked files or protected computers) from any answers to questions that you might provide. Your private information will be maintained separately at the West Haven Cooperative Studies Program Coordinating Center in accordance with the Privacy Act of 1974.
- If you take part in this study you will be asked to provide personal identifying information, including your name, address, and social security number, for purposes of compensation and applicable reimbursement for your participation. Your information will be labeled with a code instead of your name or other information that could identify you directly. The key that links the code to your identity will be kept at the VA. Only a limited number of approved VA research staff will have access to that key.
- Computers used for testing will be protected using passwords and encryption. Encryption is special coding that makes the information difficult to read without special computer programs held by the VA to translate them. The research database that contains any personal identifiers for this study will be secured so even those authorized can only access it with a username and a password. The research database for this study will be kept on a VA storage device that will not be portable.
- If you agree to be audiotaped for research purposes (another clinician will listen to 10% of the interviews), these recordings will be stored behind the VA firewall
- Your information will be used only as specified under the direction of Dr. Stein at the VA in San Diego, CA, and Dr. Gelernter at the West Haven VA in West Haven, CT. Your private information may also be used by employees of the San Diego VA Research and Development Office, as necessary, to perform their duties regarding research monitoring.

- Your data may be shared with other researchers in the VA or outside the VA. The data will be kept in a large study database. No personally identifiable information will be included in the database, only your unique identifier.
- Any publications or presentations from the study results will remain anonymous and/or be disguised with a unique identifier.
- We will retain the research records according to the instructions by the National Archives and Records Administration published in VHA's Records Control Schedule (RCS) 10-1.

You are already enrolled in the Department of Veterans Affairs (VA) Million Veteran Program (MVP). At the time of enrollment, you agreed for your data to be placed in the VA MVP Central Research Database (VA CRD), a secure VA data repository created for the collection, storage, and sharing of materials for research purposes.

Additional data collected from this new study (including but not limited to questionnaires, interviews, physical exams or assessments, medical record review, additional specimens, or data that result from specimen analysis) will be added to the VA MVP CRD to allow researchers to reuse the information. As a reminder, all of your information from the VA CRD is provided to researchers in a coded manner, so that researchers using your data cannot see your identity directly. In addition, the VA MVP CRD is maintained in a secure manner, per VA Information Security Policy.

If you have questions about this new study, please contact the San Diego research team toll free at 1-844-343-0678.

If you have any questions about your participation in MVP, please contact the **MVP Information Center at 1-866-441-6075**.

We will not share your records or identify you unless we are specifically required to do so by state or federal law. There are times when we may have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the VA Office of Research Oversight, or Cooperative Study designated monitoring committees may look at records that identify you for study monitoring purposes. No personal information will be linked to your telephone interview(s). We will use codes such as numbers that will not identify you.

Personnel from the VA Fiscal Office and U.S. Treasury will use personally identifying information (e.g., name, address, social security number) to process your Electronic Funds Transfer paperwork to provide you with compensation for your participation in this study. You may expect the same confidentiality from these groups as you would from study staff.

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.

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

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, the food and drug administration, the sponsor (VA Cooperative Studies Program and VA CSP CERC), and federal compliance officers may look at or copy portions of records that identify you.

Compensation Offered for Participation:

You will be compensated \$50 for your time and effort for taking part in the phone interview. We will ask you for some personally identifying information that includes your name, permanent address, and social security number to have a check mailed to your permanent address or an Electronic Fund Transfer be performed by the VA to your personal bank. Payment may be withheld by the US Government if you have any federal debt (i.e. child support, back taxes, defaulted student loans).

Medical Treatment or Compensation for Injury

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. You would also have the right to file any legal action, as in any instance of alleged negligence. Compensation may be payable under Title 38 USC 1151 or in some circumstances under the Federal Tort Claims Act. If there are unexpected adverse experiences that are serious, these will be reported immediately to the monitoring bodies associated with the study. In addition, the Albuquerque VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (PCC) will review adverse event data. You may expect the same confidentiality from these persons that is given to you by the investigators and their research staff.

If you experience emotional distress or any other unexpected health problem from participating in the study, you may contact your interviewer at 858-534-6436 or other staff toll free at 1-844-343-0678. This person will assess the problem and may have the study psychiatrist contact you or will put you in touch with emergency personnel or non-emergency health care professionals in your area, as appropriate. You can contact the VA Veterans Crisis Line at 1-800-273-TALK (8255).

No promises have been given to you because the results and the risks of a research study are not always known in advance. However, every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence.

Voluntary Participation

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

Right of Investigator to Terminate Participation

Study staff can terminate your participation in this study if you become acutely distressed during any part of the study. In that event, study staff will provide you with contact information for the appropriate resources. You will still be paid \$50 for your participation up to this point.

Persons to Contact

If you have questions about this research, contact the San Diego research team toll free at 1-844-343-0678.

In the event of illness or injury that you believe to be related to the study, you can call the San Diego research team toll free at 1-844-343-0678, or Murray Stein, M.D., at 1-858-534-6451. 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 1-858-642-3817, VA Research Service at 1-858-642-3657, VA Regional Counsel at 1-858-642-1540, or the VASDHS Human Research Protection Program at 1-858-642-6320.

If you wish to withdraw from this study, contact the San Diego research team toll free at 1-844-343-0678 or write to the Cooperative Studies Program at CSP Clinical Epidemiology Research Center (CERC) – CSP#575B, West Haven VA Connecticut Healthcare System, 950 Campbell Avenue, Building 35A, Mailcode 151B, West Haven, CT 06516.

Significant New Findings

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.